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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2015-4209; Directorate Identifier 2015-NM-156-AD; Amendment 39-18302; AD 2015-21-09]

RIN 2120-AA64

#### Airworthiness Directives; The Boeing Company Airplanes

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

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

**SUMMARY:** We are superseding Airworthiness Directive (AD) 2015-19-02 for all The Boeing Company Model 767 airplanes. AD 2015-19-02 required revising the maintenance or inspection program to include new airworthiness limitations. This AD continues to require a maintenance or inspection program revision, but with revised language. This AD was prompted by a determination that certain language in the airworthiness limitation was not accurate in AD 2015-19-02. We are issuing this AD to detect and correct latent failures of the fuel shutoff valve to the engine and auxiliary power unit (APU), which could result in the inability to shut off fuel to the engine and APU and, in case of certain fires, an uncontrollable fire that could lead to structural failure.

**DATES:** This AD is effective October 28, 2015.

We must receive any comments on this AD by December 10, 2015.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

#### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-4209; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Rebel Nichols, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6509; fax: 425-917-6590; email: [rebel.nichols@faa.gov](mailto:rebel.nichols@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Discussion

On September 7, 2015, we issued AD 2015-19-02, Amendment 39-18265 (80 FR 55512, September 16, 2015), for all The Boeing Company Model 767 airplanes. AD 2015-19-02 required revising the maintenance or inspection program to include new airworthiness limitations. AD 2015-19-02 resulted from reports of latently failed fuel shutoff valves discovered during fuel filter replacement. We issued AD 2015-19-02 to detect and correct latent failures of the fuel shutoff valve to the engine and APU, which could result in the inability to shut off fuel to the engine and APU and, in case of certain fires, an uncontrollable fire that could lead to structural failure.

#### Actions Since AD 2015-19-02, Amendment 39-18265 (80 FR 55512, September 16, 2015), Was Issued

Since we issued AD 2015-19-02, Amendment 39-18265 (80 FR 55512, September 16, 2015), we have determined that extraneous language was included in two locations of the text of the airworthiness limitations specified in AD 2015-19-02. In paragraph C.7.a. of the "Description" column of figure 1 to paragraph (g) of AD 2015-19-02, the text "or the APU selector switch on the overhead panel is in the ON position" is not relevant to the actions specified in that paragraph. In paragraph A.5. of the "Description" column of figure 3 to paragraph (g) of AD 2015-19-02, the text "the FUEL CONTROL switch is in the RUN position or" is not relevant to the actions specified in that paragraph.

We have determined that the language must be corrected to avoid any confusion in the paragraphs of the airworthiness limitation. We are issuing this AD to detect and correct latent failures of the fuel shutoff valve to the engine and APU, which could result in the inability to shut off fuel to the engine and APU and, in case of certain fires, an uncontrollable fire that could lead to structural failure.

#### FAA's Determination

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

#### AD Requirements

This AD requires revising the maintenance or inspection program to include new airworthiness limitations.

#### Interim Action

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

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

We are superseding AD 2015-19-02, Amendment 39-18265 (80 FR 55512, September 16, 2015), to correct inaccurate terminology in the



“Description” column of figure 1 to paragraph (g) of AD 2015–19–02 and figure 3 to paragraph (g) of AD 2015–19–02. We have made no other changes to the requirements published in AD 2015–19–02. We have determined that the changes impose no additional burden on any operator. Therefore, we find that notice and opportunity for prior public comment are unnecessary and that good cause exists for making this amendment effective in less than 30 days.

**Comments Invited**

This AD is a final rule that involves requirements affecting flight safety, and

we did not provide you with notice and an opportunity to provide your comments before it becomes effective. However, we invite you to send any written data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include the Docket Number FAA–2015–4209 and Directorate Identifier 2015–NM–156–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may

amend this AD because of those comments.

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

**Costs of Compliance**

We estimate that this AD affects 450 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Incorporating Airworthiness Limitation .....	1 work-hour × \$85 per hour = \$85 .....	\$0	\$85	\$38,250

**Authority for This Rulemaking**

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

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

**Regulatory Findings**

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 39**

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

**Adoption of the Amendment**

Accordingly, under the authority delegated to me by the Administrator, the FAA amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

**PART 39—AIRWORTHINESS DIRECTIVES**

- 1. The authority citation for part 39 continues to read as follows:  
**Authority:** 49 U.S.C. 106(g), 40113, 44701.

**§ 39.13 [Amended]**

- 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2015–19–02, Amendment 39–18265 (80 FR 55512, September 16, 2015), and adding the following new AD:

**2015–21–09 The Boeing Company:**  
 Amendment 39–18302; Docket No. FAA–2015–4209; Directorate Identifier 2015–NM–156–AD.

**(a) Effective Date**

This AD is effective October 28, 2015.

**(b) Affected ADs**

This AD replaces AD 2015–19–02, Amendment 39–18265 (80 FR 55512, September 16, 2015).

**(c) Applicability**

This AD applies to all The Boeing Company Model 767–200, –300, –300F, and –400ER series airplanes, certificated in any category.

**(d) Subject**

Air Transport Association (ATA) of America Code 28, Fuel.

**(e) Unsafe Condition**

This AD was prompted by reports of latently failed fuel shutoff valves discovered during fuel filter replacement. We are issuing this AD to detect and correct latent failures of the fuel shutoff valve to the engine and auxiliary power unit (APU), which could result in the inability to shut off fuel to the engine and APU and, in case of certain fires, an uncontrollable fire that could lead to structural failure.

**(f) Compliance**

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

**(g) Revision of Maintenance or Inspection Program**

Within 30 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to add airworthiness limitation numbers 28–AWL–ENG, 28–AWL–MOV, and 28–AWL–APU, by incorporating the information specified in figure 1, figure 2, and figure 3 to paragraph (g) of this AD into the Airworthiness Limitations Section of the Instructions for Continued Airworthiness. The initial compliance time for accomplishing the actions specified in figure 1, figure 2, and figure 3 to paragraph (g) of this AD is within 10 days after accomplishing the maintenance or inspection program revision required by this paragraph.

FIGURE 1 TO PARAGRAPH (g) OF THIS AD: ENGINE FUEL SHUTOFF VALVE (FUEL SPAR VALVE) POSITION INDICATION OPERATIONAL CHECK

AWL No.	Task	Interval	Applicability	Description
28-AWL-ENG ...	ALI	DAILY .....  INTERVAL NOTE: The operational check is not required on days when the airplane is not used in revenue service. The check must be done before further flight once the airplane is returned to revenue service.	767-200, -300, and -300F airplanes.  APPLICABILITY NOTE: Applies to airplanes with an actuator installed at the engine fuel spar valve position having part number (P/N) MA20A2027 (S343T003-56) or P/N MA30A1001 (S343T003-66).	Engine Fuel Shutoff Valve (Fuel Spar Valve) Position Indication Operational Check.  Concern: The fuel spar valve actuator design can result in airplanes operating with a failed fuel spar valve actuator that is not reported. A latently failed fuel spar valve actuator could prevent fuel shutoff to an engine. In the event of certain engine fires, the potential exists for an engine fire to be uncontrollable.  Perform one of the following checks/inspection of the fuel spar valve position (unless checked by the flightcrew in a manner approved by the principal operations inspector): A. Operational Check during engine shutdown. 1. Do an operational check of the left engine fuel spar valve actuator. a. As the L FUEL CONTROL switch on the quadrant control stand is moved to the CUTOFF position, verify the left SPAR VALVE disagreement light on the quadrant control stand illuminates and then goes off. b. If the test fails (light fails to illuminate), before further flight, repair faults as required (refer to Boeing airplane maintenance manual (AMM) 28-22-11). 2. Do an operational check of the right engine fuel spar valve actuator. a. As the R FUEL CONTROL switch on the quadrant control stand is moved to the CUTOFF position, verify the right SPAR VALVE disagreement light on the quadrant control stand illuminates and then goes off. b. If the test fails (light fails to illuminate), before further flight, repair faults as required (refer to Boeing AMM 28-22-11). B. Operational check during engine start. 1. Do an operational check of the left engine fuel spar valve actuator. a. As the L FUEL CONTROL switch on the quadrant control stand is moved to the RUN (or RICH) position, verify the left SPAR VALVE disagreement light on the quadrant control stand illuminates and then goes off. b. If the test fails (light fails to illuminate), before further flight, repair faults as required (refer to Boeing AMM 28-22-11). 2. Do an operational check of the right engine fuel spar valve actuator. a. As the R FUEL CONTROL switch on the quadrant control stand is moved to the RUN (or RICH) position, verify the right SPAR VALVE disagreement light on the quadrant control stand illuminates and then goes off. b. If the test fails (light fails to illuminate), before further flight, repair faults as required (refer to Boeing AMM 28-22-11). C. Operational check without engine operation. 1. Supply electrical power to the airplane using standard practices. 2. Make sure all fuel pump switches on the Overhead Panel are in the OFF position. 3. If the auxiliary power unit (APU) is running, open and collar the L FWD FUEL BOOST PUMP (C00372) circuit breaker on the Main Power Distribution Panel. 4. Make sure LEFT and RIGHT ENG FIRE switches on the Aft Aisle Stand are in the NORMAL (IN) position. 5. Make sure L and R ENG START Selector Switches on the Overhead Panel, are in the OFF position. 6. Do an operational check of the left engine fuel spar valve actuator.

FIGURE 1 TO PARAGRAPH (g) OF THIS AD: ENGINE FUEL SHUTOFF VALVE (FUEL SPAR VALVE) POSITION INDICATION OPERATIONAL CHECK—Continued

AWL No.	Task	Interval	Applicability	Description
				<p>a. Move L FUEL CONTROL switch on the quadrant control stand to the RUN position and wait approximately 10 seconds. NOTE: It is normal under this test condition for the ENG VALVE disagreement light on the quadrant control stand to stay illuminated.</p> <p>b. Move L FUEL CONTROL switch on the quadrant control stand to the CUTOFF position.</p> <p>c. Verify the left SPAR VALVE disagreement light on the quadrant control stand illuminates and then goes off.</p> <p>d. If the test fails (light fails to illuminate), before further flight, repair faults as required (refer to Boeing AMM 28-22-11).</p> <p>7. Do an operational check of the right engine fuel spar valve actuator.</p> <p>a. Move R FUEL CONTROL switch on the quadrant control stand to the RUN position and wait approximately 10 seconds once the FUEL CONTROL switch is in the RUN position. NOTE: It is normal under this test condition for the ENG VALVE disagreement light on the quadrant control stand to stay illuminated.</p> <p>b. Move R FUEL CONTROL switch on the quadrant control stand to the CUTOFF position.</p> <p>c. Verify the right SPAR VALVE disagreement light on the quadrant control stand illuminates and then goes off.</p> <p>d. If the test fails (light fails to illuminate), before further flight, repair faults as required (refer to Boeing AMM 28-22-11).</p> <p>8. If the L FWD FUEL BOOST PUMP circuit breaker was collared in step 3, remove collar and close.</p> <p>D. Perform an inspection of the fuel spar valve actuator position. NOTE: This inspection may be most useful whenever the SPAR VALVE light does not function properly.</p> <p>1. Make sure the L FUEL CONTROL switch on the quadrant control stand is in the CUTOFF position. NOTE: It is not necessary to cycle the FUEL CONTROL switch to do this inspection.</p> <p>2. Inspect the left engine fuel spar valve actuator located in the left rear spar. NOTE: The Fuel Spar Valve actuators are located behind main gear doors on the rear spar.</p> <p>a. Verify the manual override handle on the engine fuel spar valve actuator is in the CLOSED position.</p> <p>b. Repair or replace any fuel spar valve actuator that is not in the CLOSED position (refer to Boeing AMM 28-22-11).</p> <p>3. Make sure the R FUEL CONTROL switch on the quadrant control stand is in the CUTOFF position. NOTE: It is not necessary to cycle the FUEL CONTROL switch to do this inspection.</p> <p>4. Inspect the right engine fuel spar valve actuator located in the right rear spar. NOTE: The Fuel Spar Valve actuators are located behind main gear doors on the rear spar.</p> <p>a. Verify the manual override handle on the engine fuel spar valve actuator is in the CLOSED position.</p> <p>b. Repair or replace any fuel spar valve actuator that is not in the CLOSED position (refer to Boeing AMM 28-22-11).</p>

FIGURE 2 TO PARAGRAPH (G) OF THIS AD: ENGINE FUEL SHUTOFF VALVE (FUEL SPAR VALVE) ACTUATOR INSPECTION

AWL No.	Task	Interval	Applicability	Description
28-AWL-MOV ....	ALI	10 DAYS .....  INTERVAL NOTE: The inspection is not required on days when the airplane is not used in revenue service. The inspection must be done before further flight if it has been 10 or more calendar days since last inspection.	767-400ER series airplanes. APPLICABILITY NOTE: Applies to airplanes with an actuator installed at the engine fuel spar valve position having part number (P/N) MA20A2027 (S343T003-56) or P/N MA30A1001 (S343T003-66).	Engine Fuel Shutoff Valve (Fuel Spar Valve) Actuator Inspection. Concern: The fuel spar valve actuator design can result in airplanes operating with a failed fuel spar valve actuator that is not reported. A latently failed fuel spar valve actuator would prevent fuel shutoff to an engine. In the event of certain engine fires, the potential exists for an engine fire to be uncontrollable. Perform an inspection of the fuel spar valve actuator position. NOTE: The fuel spar valve actuators are located behind main gear doors on the rear spar. 1. Make sure the L FUEL CONTROL switch on the quadrant control stand is in the CUTOFF position. NOTE: It is not necessary to cycle the FUEL CONTROL switch to do this inspection. 2. Inspect the left engine fuel spar valve actuator located in the left rear spar. a. Verify the manual override handle on the engine fuel spar valve actuator is in the CLOSED position. b. Repair or replace any fuel spar valve actuator that is not in the CLOSED position (refer to Boeing AMM 28-22-11). 3. Make sure the R FUEL CONTROL switch on the quadrant control stand is in the CUTOFF position. NOTE: It is not necessary to cycle the FUEL CONTROL switch to do this inspection. 4. Inspect the right engine fuel spar valve actuator located in the right rear spar. a. Verify the manual override handle on the engine fuel spar valve actuator is in the CLOSED position. b. Repair or replace any fuel spar valve actuator that is not in the CLOSED position (refer to Boeing AMM 28-22-11).

FIGURE 3 TO PARAGRAPH (G) OF THIS AD: AUXILIARY POWER UNIT (APU) FUEL SHUTOFF VALVE POSITION INDICATION OPERATIONAL CHECK

AWL No.	Task	Interval	Applicability	Description
28-AWL-APU ...	ALI	10 DAYS .....  INTERVAL NOTE: The operational check is not required on days when the airplane is not used in revenue service. The operational check must be done before further flight with an operational APU if it has been 10 or more calendar days since last check.	ALL ..... APPLICABILITY NOTE: Applies to airplanes with an actuator installed at the APU fuel shutoff valve position having part number (P/N) MA20A2027 (S343T003-56) or MA30A1001 (S343T003-66).	APU Fuel Shutoff Valve Position Indication Operational Check. Concern: The APU fuel shutoff valve actuator design can result in airplanes operating with a failed APU fuel shutoff valve actuator that is not reported. A latently failed APU fuel shutoff valve actuator could prevent fuel shutoff to the APU. In the event of certain APU fires, the potential exists for an APU fire to be uncontrollable. Perform the operational check of the APU fuel shutoff valve position indication (unless checked by the flightcrew in a manner approved by the principal operations inspector). A. Do an operational check of the APU fuel shutoff valve position indication. 1. If the APU is running, unload and shut down the APU using standard practices. 2. Supply electrical power to the airplane using standard practices. 3. Make sure the APU FIRE switch on the Aft Aisle Stand is in the NORMAL (IN) position. 4. Make sure there is at least 1,000 lbs (500 kgs) of fuel in the Left Main Tank. 5. Move APU Selector switch on the Overhead Panel to the ON position and wait approximately 10 seconds once the APU selector switch on the overhead panel is in the ON position. 6. Move the APU Selector switch on the Overhead Panel to the OFF position.

FIGURE 3 TO PARAGRAPH (G) OF THIS AD: AUXILIARY POWER UNIT (APU) FUEL SHUTOFF VALVE POSITION INDICATION OPERATIONAL CHECK—Continued

AWL No.	Task	Interval	Applicability	Description
				7. Verify the APU FAULT light on the Overhead Panel illuminates and then goes off. 8. If the test fails (light fails to illuminate), before further flight requiring APU availability, repair faults as required (refer to Boeing AMM 28–25–02). NOTE: Dispatch may be permitted per MMEL 28–25–02 if APU is not required for flight.

**(h) No Alternative Actions or Intervals**

After accomplishment of the maintenance or inspection program revision required by paragraph (g) of this AD, no alternative actions (e.g., inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

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

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

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

**(j) Related Information**

For more information about this AD, contact Rebel Nichols, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6509; fax: 425–917–6590; email: *rebel.nichols@faa.gov*.

**(k) Material Incorporated by Reference**

None.

Issued in Renton, Washington, on October 16, 2015.

**Jeffrey E. Duven,**

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

[FR Doc. 2015–26983 Filed 10–23–15; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

[Docket No. FAA–2015–0933; Directorate Identifier 2014–NM–098–AD; Amendment 39–18297; AD 2015–21–05]

RIN 2120–AA64

**Airworthiness Directives; Fokker Services B.V. Airplanes**

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

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for all Fokker Services B.V. Model F.27 Mark 200, 300, 400, 500, 600, and 700 airplanes. This AD was prompted by a design review, which revealed that no controlled bonding provisions are present on a number of critical locations inside the fuel tank or connected to the fuel tank wall; and no anti-spray cover is installed on the fuel shut-off valve (FSOV) in both wings. This AD requires installing additional bonding provisions in the fuel tank, installing an anti-spray cover on the FSOV, and revising the airplane maintenance program by incorporating fuel airworthiness limitation items and critical design configuration control limitations. We are issuing this AD to prevent an ignition source in the fuel tank vapor space, which could result in a fuel tank explosion and consequent loss of the airplane.

**DATES:** This AD becomes effective November 30, 2015.

**ADDRESSES:** You may examine the AD docket on the Internet at *http://www.regulations.gov/#/docketDetail;D=FAA-2015-0933* or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1137; fax 425–227–1149.

**SUPPLEMENTARY INFORMATION:**

**Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Fokker Services B.V. Model F.27 Mark 200, 300, 400, 500, 600, and 700 airplanes. The NPRM published in the **Federal Register** on May 4, 2015 (80 FR 25247).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0099, dated April 30, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for all Fokker Services B.V. Model F.27 Mark 200, 300, 400, 500, 600, and 700 airplanes. The MCAI states:

Prompted by an accident \* \* \*, the FAA published Special Federal Aviation Regulation (SFAR) 88 [(66 FR 23086, May 7, 2001)], and the Joint Aviation Authorities (JAA) published Interim Policy INT/POL/25/12.

The review conducted by Fokker Services on the Fokker 27 design in response to these regulations revealed that no controlled bonding provisions are present on a number of critical locations, inside the fuel tank or connected to the fuel tank wall, and no anti-spray cover is installed on the Fueling Shut-Off Valve (FSOV) in both wings.

This condition, if not corrected, could create an ignition source in the fuel tank vapour space, possibly resulting in a fuel tank explosion and consequent loss of the aeroplane.

To address this potential unsafe condition, Fokker Services developed a set of bonding modifications and anti-spray covers, [and] introduced with Service Bulletin (SB) SBF27–28–071 Revision 1 (R1), that require opening of the fuel tank access panels. More information on this subject can be found in Fokker Services All Operators Message AOF27.043#03.

For the reasons described above, this [EASA] AD requires installation of additional bonding provisions, and of anti-spray covers on the FSOV, that require opening of the fuel tank access panels.

Required actions also include revising the airplane maintenance program by incorporating fuel airworthiness limitation items and critical design configuration control limitations. You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-0933.

#### Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (80 FR 25247, May 4, 2015) or on the determination of the cost to the public.

#### Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting this AD as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (80 FR 25247, May 4, 2015) for correcting the unsafe condition; and

- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 25247, May 4, 2015).

#### Costs of Compliance

We estimate that this AD affects 15 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

#### ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Installation of bonding provisions, anti-spray cover, and maintenance program revision.	70 work-hours × \$85 per hour = \$5,950.	\$0	\$5,950	\$89,250

#### Authority for This Rulemaking

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

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

#### Regulatory Findings

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

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

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.

#### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov/#/docketDetail;D=FAA-2015-0933>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800-647-5527) is in the ADDRESSES section.

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

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

#### PART 39—AIRWORTHINESS DIRECTIVES

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

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

#### § 39.13 [Amended]

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

**2015-21-05 Fokker Services B.V.:**

Amendment 39-18297; Docket No.

FAA-2015-0933; Directorate Identifier 2014-NM-098-AD.

#### (a) Effective Date

This AD becomes effective November 30, 2015.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to Fokker Services B.V. Model F.27 Mark 200, 300, 400, 500, 600, and 700 airplanes, certificated in any category, all serial numbers.

#### (d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

#### (e) Reason

This AD was prompted by a design review, which revealed that no controlled bonding provisions are present on a number of critical locations inside the fuel tank or connected to the fuel tank wall; and no anti-spray cover is installed on the fuel shut-off valve (FSOV) in both wings. We are issuing this AD to prevent an ignition source in the fuel tank vapor space, which could result in a fuel tank explosion and consequent loss of the airplane.

#### (f) Compliance

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

#### (g) Installation of Bonding Provisions and Anti-spray Cover

At the next scheduled opening of the fuel tanks after the effective date of this AD, but no later than 84 months after the effective date of this AD: Install additional bonding provisions at the applicable locations, and install an anti-spray cover on the FSOV in both wings, using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA.

**(h) Revision of Maintenance or Inspection Program**

Within 30 days after installing the bonding provisions and anti-spray cover specified in paragraph (g) of this AD: Revise the airplane maintenance or inspection program, as applicable, by incorporating fuel airworthiness limitation items and Critical Design Configuration Control Limitations (CDCCLs), using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA.

**(i) No Alternative Actions, Intervals, and/or CDCCLs**

After accomplishing the revision required by paragraph (h) of this AD, no alternative actions (e.g., inspections), intervals, or CDCCLs may be used unless the actions, intervals, or CDCCLs are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (j)(1) of this AD.

**(j) Other FAA AD Provisions**

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1137; fax 425-227-1137. Information may be emailed to: [9-ANM-116-AMOC-REQUESTS@faa.gov](mailto:9-ANM-116-AMOC-REQUESTS@faa.gov). Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the EASA; or Fokker Services B.V.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

**(k) Related Information**

Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014-0099, dated April 30, 2014, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov/>#!documentDetail;D=FAA-2015-0933-0003.

**(l) Material Incorporated by Reference**

None.

Issued in Renton, Washington, on October 11, 2015.

**Jeffrey E. Duven,**

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

[FR Doc. 2015-26612 Filed 10-23-15; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

**[Docket No. FAA-2015-3940; Directorate Identifier 2015-SW-065-AD; Amendment 39-18300; AD 2015-19-51]**

**RIN 2120-AA64**

**Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters**

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

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

**SUMMARY:** We are publishing a new airworthiness directive (AD) for Sikorsky Aircraft Corporation Model S-76A, S-76B, S-76C, and S-76D helicopters, which was sent previously to all known U.S. owners and operators of these helicopters. This AD requires inspecting the main rotor (M/R) and tail rotor (T/R) pushrod assemblies and the jamnuts, and applying slippage marks across the pushrod tubes and jamnuts. This AD is prompted by an accident of a Sikorsky Aircraft Corporation Model S-76C helicopter. During preliminary investigation, a failed pushrod assembly was identified. These actions are intended to prevent loss of M/R or T/R flight control and subsequent loss of control of the helicopter.

**DATES:** This AD becomes effective November 10, 2015 to all persons except those persons to whom it was made immediately effective by Emergency AD 2015-19-51, issued on September 14, 2015, which contains the requirements of this AD.

We must receive comments on this AD by December 28, 2015.

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

- *Federal eRulemaking Docket:* Go to <http://www.regulations.gov>. Follow the online instructions for sending your comments electronically.

- *Fax:* 202-493-2251.

- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey

Avenue SE., Washington, DC 20590-0001.

- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**Examining the AD Docket**

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-3940; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1-800-Winged-S or 203-416-4299; email [sikorskywcs@sikorsky.com](mailto:sikorskywcs@sikorsky.com). You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177.

**FOR FURTHER INFORMATION CONTACT:** Blaine Williams, Aerospace Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, Massachusetts 01803; telephone (781) 238-7161; email [blaine.williams@faa.gov](mailto:blaine.williams@faa.gov).

**SUPPLEMENTARY INFORMATION:****Comments Invited**

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should

submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

#### Discussion

On September 14, 2015, we issued Emergency AD 2015–19–51 for Sikorsky Aircraft Corporation Model S–76A, S–76B, S–76C, and S–76D helicopters with M/R servo input control pushrod (pushrod) assembly part number (P/N) 76400–00034–059 or T/R pushrod assembly P/N 76400–00014–071 installed. Emergency AD 2015–19–51 requires inspecting the M/R forward, aft, and lateral pushrod assemblies, the T/R pushrod assembly, and the jamnuts, and applying slippage marks across the pushrod tubes and jamnuts. Emergency AD 2015–19–51 was sent previously to all known U.S. owners and operators of these helicopters and was prompted by an accident of a Sikorsky Aircraft Corporation Model S–76C helicopter in which a failed pushrod assembly was identified during preliminary investigation. Separation of the pushrod tube and the control rod end with bearing was found.

#### FAA's Determination

We are issuing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other helicopters of these same type designs.

#### Related Service Information

Sikorsky issued Alert Service Bulletin No. 76–67–57, Basic Issue, dated September 10, 2015 (ASB), which specifies a one-time inspection of the M/R forward, aft, and lateral pushrod assemblies, the T/R pushrod assembly, and the jamnuts for proper installation, condition, and security. If a pushrod or jamnut does not meet criteria specified in the inspection, the ASB specifies replacing the assembly. The ASB also specifies applying two slippage marks across each M/R and T/R pushrod tube and jamnut. Further, the ASB references the applicable maintenance manual for a new recurring inspection of the slippage marks.

#### AD Requirements

This AD requires, within five hours time-in-service (TIS), inspecting each M/R and T/R pushrod assembly by inspecting the position of the control rod end in the pushrod tube. If the

lockwire passes through the inspection hole, this AD requires replacing the pushrod assembly. If the lockwire does not pass through the inspection hole, this AD requires inspecting the jamnut to determine seating position against the pushrod and whether the jamnut can be turned with finger pressure. If the jamnut is not seated against the pushrod or is loose, this AD requires replacing the pushrod assembly. This AD also requires, both for those pushrod assemblies that are replaced and for those that pass the inspections, applying two slippage marks across each M/R and T/R pushrod tube and jamnut.

#### Interim Action

We consider this AD to be an interim action as the accident investigation is ongoing. If additional action is later identified, we might consider further rulemaking.

#### Costs of Compliance

We estimate that this AD affects 198 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD at an average labor rate of \$85 per work-hour. It takes about 1 work-hour to inspect the pushrod assemblies and jamnut for a cost of \$85 per helicopter and \$16,830 for the U.S. fleet. It takes a minimal amount of time to apply the slippage marks for a negligible cost. Replacing a pushrod assembly takes about 1.5 work-hours for a labor cost of \$128. Parts for an M/R pushrod assembly cost \$2,411 for a total replacement cost of \$2,539. Parts for a T/R pushrod assembly cost \$1,905 for a total replacement cost of \$2,033.

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

Providing an opportunity for public comments prior to adopting these AD requirements would delay implementing the safety actions needed to correct this known unsafe condition. Therefore, we found and continue to find that the risk to the flying public justifies waiving notice and comment prior to the adoption of this rule because the previously described unsafe condition can adversely affect the controllability of the helicopter and the initial required action must be accomplished within five hours TIS.

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment before issuing this AD were impracticable and contrary to public interest and good cause existed to make the AD effective immediately by Emergency AD 2015–19–51, issued on September 14, 2015, to all known U.S.

owners and operators of these helicopters. These conditions still exist and the AD is hereby published in the **Federal Register** as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective to all persons.

#### Authority for This Rulemaking

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

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

#### Regulatory Findings

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

For the reasons discussed, I certify that this AD:

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

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

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator,



the FAA amends 14 CFR part 39 as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

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

#### 2015–19–51 Sikorsky Aircraft

**Corporation:** Amendment 39–18300; Docket No. FAA–2015–3940; Directorate Identifier 2015–SW–065–AD.

#### (a) Applicability

This AD applies to Model S–76A, S–76B, S–76C, and S–76D helicopters with main rotor (M/R) servo input control pushrod (pushrod) assembly part number (P/N) 76400–00034–059 or tail rotor (T/R) pushrod assembly P/N 76400–00014–071 installed, certificated in any category.

#### (b) Unsafe Condition

This AD defines the unsafe condition as a loose jamnut. This condition could result in failure of a pushrod assembly, loss of M/R or T/R flight control, and subsequent loss of control of the helicopter.

#### (c) Effective Date

This AD becomes effective November 10, 2015 to all persons except those persons to whom it was made immediately effective by Emergency AD 2015–19–51, issued on September 14, 2015, which contains the requirements of this AD.

#### (d) Compliance

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

#### (e) Required Actions

Within five hours time-in-service:

(1) Inspect each pushrod end to determine whether a 0.020 inch diameter lockwire can pass through the inspection hole.

(i) If the lockwire passes through the inspection hole, replace the pushrod assembly.

(ii) If the lockwire does not pass through the inspection hole, inspect the jamnut to determine whether it is seated against the pushrod and whether it can be turned with finger pressure. If the jamnut is not seated against the pushrod or can be turned with finger pressure, replace the pushrod assembly.

(2) Apply two slippage marks across each pushrod tube and jamnut as follows:

(i) Clean the area where a slippage mark is to be applied.

(ii) Apply two slippage marks across the pushrod tube and jamnut, parallel and on opposite sides of each other. Each slippage mark must extend at least 0.5 inch onto the pushrod tube and must not cover the inspection hole. Figures 2 and 4 of Sikorsky

Alert Service Bulletin No. 76–67–57, Basic Issue, dated September 10, 2015, illustrate slippage marks across a pushrod tube and jamnut.

#### (f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Blaine Williams, Aerospace Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, Massachusetts 01803; telephone (781) 238–7161; email [blaine.williams@faa.gov](mailto:blaine.williams@faa.gov).

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

#### (g) Additional Information

Sikorsky Alert Service Bulletin No. 76–67–57, Basic Issue, dated September 10, 2015, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S or 203–416–4299; email [sikorskywcs@sikorsky.com](mailto:sikorskywcs@sikorsky.com). You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

#### (h) Subject

Joint Aircraft Service Component (JASC) Code: 2700, Flight Control System.

Issued in Fort Worth, Texas, on October 9, 2015.

#### Lance T. Gant,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2015–26949 Filed 10–23–15; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA–2015–4208; Directorate Identifier 2015–NM–152–AD; Amendment 39–18303; AD 2015–21–10]

**RIN 2120–AA64**

#### Airworthiness Directives; The Boeing Company Airplanes

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

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

**SUMMARY:** We are superseding Airworthiness Directive (AD) 2015–19–03 for all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. AD 2015–19–03 required revising the maintenance or inspection program to include new airworthiness limitations. This AD continues to require a maintenance or inspection program revision, but with revised language. This AD was prompted by a determination that certain language in the airworthiness limitation was not accurate in AD 2015–19–03. We are issuing this AD to detect and correct latent failures of the fuel shutoff valve to the engine, which could result in the inability to shut off fuel to the engine and, in case of certain engine fires, an uncontrollable fire that could lead to wing failure.

**DATES:** This AD is effective October 28, 2015.

We must receive any comments on this AD by December 10, 2015.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202–493–2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

#### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2015–4208; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

#### FOR FURTHER INFORMATION CONTACT:

Rebel Nichols, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6509; fax:

425-917-6590; email: *rebel.nichols@faa.gov*.

**SUPPLEMENTARY INFORMATION:**

**Discussion**

On September 7, 2015, we issued AD 2015-19-03, Amendment 39-18266 (80 FR 55527, September 16, 2015), for all The Boeing Company Model 737-600, -700, -700C, -800, -900, and -900ER series airplanes. AD 2015-19-03 required revising the maintenance or inspection program to include new airworthiness limitations. AD 2015-19-03 resulted from reports of latently failed fuel shutoff valves discovered during fuel filter replacement. We issued AD 2015-19-03 to detect and correct latent failures of the fuel shutoff valve to the engine, which could result in the inability to shut off fuel to the engine and, in case of certain engine fires, an uncontrollable fire that could lead to wing failure.

**Actions Since AD 2015-19-03, Amendment 39-18266 (80 FR 55527, September 16, 2015), Was Issued**

Since we issued AD 2015-19-03, Amendment 39-18266 (80 FR 55527, September 16, 2015), we have determined that certain language in the airworthiness limitation was not accurate. In paragraph D. of the "Description" column of figure 1 to paragraph (g) of AD 2015-19-03, the "START LEVER" is identified as a "FUEL CONTROL switch" in four locations. In addition, in two locations in paragraph D. of the "Description" column of figure 1 to paragraph (g) of AD 2015-19-03, it specifies that fuel spar valve actuators are located in the "rear spar," but the correct location is the "front spar." Also, in two locations

in paragraph D. of the "Description" column of figure 1 to paragraph (g) of AD 2015-19-03, the term "quadrant" is used to describe the control stand, but the correct terminology is "CONTROL STAND." We have determined that the language must be corrected to avoid any confusion in the paragraphs of the airworthiness limitation. We are issuing this AD to detect and correct latent failures of the fuel shutoff valve to the engine, which could result in the inability to shut off fuel to the engine and, in case of certain engine fires, an uncontrollable fire that could lead to wing failure.

**FAA's Determination**

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

**AD Requirements**

This AD requires revising the maintenance or inspection program to include new airworthiness limitations.

**Interim Action**

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

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

We are superseding AD 2015-19-03, Amendment 39-18266 (80 FR 55527, September 16, 2015), to correct inaccurate terminology in paragraph D. of the "Description" column of figure 1

to paragraph (g) of AD 2015-19-03. We have made no other changes to the requirements published in AD 2015-19-03. We have determined that the changes impose no additional burden on any operator. Therefore, we find that notice and opportunity for prior public comment are unnecessary and that good cause exists for making this amendment effective in less than 30 days.

**Comments Invited**

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments before it becomes effective. However, we invite you to send any written data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include the Docket Number FAA-2015-4208 and Directorate Identifier 2015-NM-152-AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

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

**Costs of Compliance**

We estimate that this AD affects 1,244 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Incorporating Airworthiness Limitation .....	1 work-hour × \$85 per hour = \$85 .....	\$0	\$85	\$105,740

**Authority for This Rulemaking**

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

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with

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

**Regulatory Findings**

This AD will not have federalism implications under Executive Order

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

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

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

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

**List of Subjects in 14 CFR Part 39**

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

**Adoption of the Amendment**

Accordingly, under the authority delegated to me by the Administrator, the FAA amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§ 39.13 [Amended]**

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD)

2015–19–03, Amendment 39–18266 (80 FR 55527, September 16, 2015), and adding the following new AD:

**2015–21–10 The Boeing Company:**  
Amendment 39–18303; Docket No. FAA–2015–4208; Directorate Identifier 2015–NM–152–AD.

**(a) Effective Date**

This AD is effective October 28, 2015.

**(b) Affected ADs**

This AD replaces AD 2015–19–03, Amendment 39–18266 (80 FR 55527, September 16, 2015).

**(c) Applicability**

This AD applies to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, certificated in any category.

**(d) Subject**

Air Transport Association (ATA) of America Code 2823, Fuel Selector/Shutoff Valve.

**(e) Unsafe Condition**

This AD was prompted by reports of latently failed fuel shutoff valves discovered during fuel filter replacement. We are issuing this AD to detect and correct latent failures

of the fuel shutoff valve to the engine, which could result in the inability to shut off fuel to the engine and, in case of certain engine fires, an uncontrollable fire that could lead to wing failure.

**(f) Compliance**

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

**(g) Revision of Maintenance or Inspection Program**

Within 30 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to add airworthiness limitation number 28–AWL–MOV, “Engine Fuel Shutoff Valve (Fuel Spar Valve) Position Indication Operational Check,” by incorporating the information specified in figure 1 to paragraph (g) of this AD into the Airworthiness Limitations Section of the Instructions for Continued Airworthiness. The initial compliance time for accomplishing the actions specified in 28–AWL–MOV is within 10 days after accomplishing the maintenance or inspection program revision required by this paragraph.

FIGURE 1 TO PARAGRAPH (g) OF THIS AD—ENGINE FUEL SHUTOFF VALVE (FUEL SPAR VALVE) POSITION INDICATION OPERATIONAL CHECK

AWL No.	Task	Interval	Applicability	Description
28–AWL–MOV .....	ALI	DAILY .....	737–600, –700, –700C, –800, –900, and –900ER series airplanes.  APPLICABILITY NOTE: Only applies to airplanes with a fuel spar valve actuator having part number MA20A2027 (S343T003–56) or MA30A1001 (S343T003–66) installed at the engine fuel spar valve positions.	Engine Fuel Shutoff Valve (Fuel Spar Valve) Position Indication Operational Check.  Concern: The fuel spar valve actuator design can result in airplanes operating with a failed fuel spar valve actuator that is not reported. A latently failed fuel spar valve actuator could prevent fuel shutoff to an engine. In the event of certain engine fires, the potential exists for an engine fire to be uncontrollable. Perform one of the following checks of the engine fuel spar valve position (unless checked by the flightcrew in a manner approved by the principal operations inspector): A. Operational Check during engine shutdown. 1. Do an operational check of the left engine fuel spar valve actuator. a. As the ENG 1 START LEVER on the CONTROL STAND is moved to the CUTOFF position, verify the SPAR VALVE CLOSED indication light on the OVERHEAD PANEL for No.1 Engine changes from OFF to BRIGHT then DIM. b. If the test fails (bright light fails to illuminate), before further flight, repair faults as required (refer to Boeing Aircraft Maintenance Manual (AMM) 28–22–11). 2. Do an operational check of the right engine fuel spar valve actuator. a. As the ENG 2 START LEVER on the CONTROL STAND is moved to the CUTOFF position, verify the SPAR VALVE CLOSED indication light on the OVERHEAD PANEL for No. 2 Engine changes from OFF to BRIGHT then DIM.

FIGURE 1 TO PARAGRAPH (g) OF THIS AD—ENGINE FUEL SHUTOFF VALVE (FUEL SPAR VALVE) POSITION INDICATION OPERATIONAL CHECK—Continued

AWL No.	Task	Interval	Applicability	Description
				<p>b. If the test fails (bright light fails to illuminate), before further flight, repair faults as required (refer to Boeing AMM 28–22–11).</p> <p>B. Operational check during engine start.</p> <p>1. Do an operational check of the left engine fuel spar valve actuator.</p> <p>a. As the ENG 1 START LEVER on the CONTROL STAND is moved to the IDLE position, verify the SPAR VALVE CLOSED indication light on the OVERHEAD PANEL for No. 1 Engine changes from DIM to BRIGHT then OFF.</p> <p>b. If the test fails (bright light fails to illuminate), before further flight, repair faults as required (refer to Boeing AMM 28–22–11).</p> <p>2. Do an operational check of the right engine fuel spar valve actuator.</p> <p>a. As the ENG 2 START LEVER on the CONTROL STAND is moved to the IDLE position, verify the SPAR VALVE CLOSED indication light on the OVERHEAD PANEL for No. 2 Engine changes from DIM to BRIGHT then OFF.</p> <p>b. If the test fails (bright light fails to illuminate), before further flight, repair faults as required (refer to Boeing AMM 28–22–11).</p> <p>C. Operational check without engine operation.</p> <p>1. Supply electrical power to airplane using standard practices.</p> <p>2. Make sure No. 1 and No. 2 Engine FIRE switches on the Aft Electronic Panel are in the NORMAL (IN) position.</p> <p>3. Make sure No. 1 and No. 2 Engine Start Switches on the Forward Overhead Panel are in the OFF or AUTO position.</p> <p>4. Do an operational check to the left engine fuel spar valve actuator.</p> <p>a. Move ENG 1 START LEVER on the CONTROL STAND to the IDLE position and wait approximately 10 seconds.</p> <p>NOTE: It is normal under this test condition for the ENG VALVE CLOSED indication light on the OVERHEAD PANEL to transition from DIM to BRIGHT and stay BRIGHT.</p> <p>b. Move ENG 1 START LEVER on the CONTROL STAND to the CUTOFF position.</p> <p>c. Verify the SPAR VALVE CLOSED indication light on the OVERHEAD PANEL for No. 1 Engine changes from OFF to BRIGHT then DIM.</p> <p>d. If the test fails (bright light fails to illuminate), before further flight, repair faults as required (refer to Boeing AMM 28–22–11).</p> <p>5. Do an operational check of the right engine fuel spar valve actuator.</p> <p>a. Move ENG 2 START LEVER on the CONTROL STAND to the IDLE position and wait approximately 10 seconds.</p> <p>NOTE: It is normal under this test condition for the ENG VALVE CLOSED indication light on the OVERHEAD PANEL to transition from DIM to BRIGHT and stay BRIGHT.</p> <p>b. Move ENG 2 START LEVER on the CONTROL STAND to the CUTOFF position.</p> <p>c. Verify the SPAR VALVE CLOSED indication light on the OVERHEAD PANEL for No.2 Engine changes from OFF to BRIGHT then DIM.</p> <p>d. If the test fails (bright light fails to illuminate), before further flight, repair faults as required (refer to Boeing AMM 28–22–11).</p> <p>D. Perform an inspection of the engine fuel spar valve actuator position.</p>

FIGURE 1 TO PARAGRAPH (g) OF THIS AD—ENGINE FUEL SHUTOFF VALVE (FUEL SPAR VALVE) POSITION INDICATION OPERATIONAL CHECK—Continued

AWL No.	Task	Interval	Applicability	Description
				<p>NOTE: This inspection may be used whenever the SPAR VALVE light does not function properly.</p> <ol style="list-style-type: none"> <li>1. Make sure the ENG 1 START LEVER on the CONTROL STAND is in the CUTOFF position. NOTE: It is not necessary to cycle the START LEVER to do this inspection.</li> <li>2. Inspect the left engine fuel spar valve actuator located in the left front spar. NOTE: The left engine fuel spar valve actuator is on the left wing front spar outboard of the engine strut. Access is through access panel 521BB on the left wing leading edge.                         <ol style="list-style-type: none"> <li>a. Verify the manual override handle on the engine fuel spar valve actuator is in the CLOSED position.</li> <li>b. Repair or replace any engine fuel spar valve actuator that is not in the CLOSED position (refer to Boeing AMM 28-22-11).</li> </ol> </li> <li>3. Make sure the ENG 2 START LEVER on the CONTROL STAND is in the CUTOFF position. NOTE: It is not necessary to cycle the START LEVER to do this inspection.</li> <li>4. Inspect the right engine fuel spar valve actuator located in the right front spar. NOTE: The right engine fuel spar valve actuator is on the right wing front spar outboard of the engine strut. Access is through access panel 621BB on the right wing leading edge.                         <ol style="list-style-type: none"> <li>a. Verify the manual override handle on the engine fuel spar valve actuator is in the CLOSED position.</li> <li>b. Repair or replace any engine fuel spar valve actuator that is not in the CLOSED position (refer to Boeing AMM 28-22-11).</li> </ol> </li> </ol>

**(h) No Alternative Actions or Intervals**

After accomplishment of the maintenance or inspection program revision required by paragraph (g) of this AD, no alternative actions (e.g., inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

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

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

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

**(j) Related Information**

For more information about this AD, contact Rebel Nichols, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6509; fax: 425-917-6590; email: *rebel.nichols@faa.gov*.

**(k) Material Incorporated by Reference**

None.

Issued in Renton, Washington, on October 16, 2015.

**Jeffrey E. Duven,**

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

[FR Doc. 2015-26992 Filed 10-23-15; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF HOMELAND SECURITY**

**U.S. Customs and Border Protection**

**DEPARTMENT OF THE TREASURY**

**19 CFR Parts 4, 7, 10, 12, 18, 19, 24, 54, 102, 113, 123, 125, 128, 132, 134, 141, 142, 143, 144, 145, 146, 148, 151, 152, 158, 163, 174, 181, and 191**

[CBP Dec. No. 15-14; USCBP-2015-0045]

RIN 1515-AE03

**Automated Commercial Environment (ACE) Filings for Electronic Entry/Entry Summary (Cargo Release and Related Entry); Correction**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

**ACTION:** Interim final rule; correction.

**SUMMARY:** U.S. Customs and Border Protection (CBP) published an Interim Final Rule (CBP Dec. 15-14) on October 13, 2015, in the **Federal Register**, which amends the CBP regulations to reflect

that on November 1, 2015, the Automated Commercial Environment (ACE) will be a CBP-authorized Electronic Data Interchange (EDI) System. That document erroneously included language in Amendatory Instruction 38 that was not consistent with the text of the existing CFR. This document corrects the text in Amendatory Instruction 38.

**DATES:** Effective November 1, 2015. The effective date for the interim final rule, published October 13, 2015 (80 FR 61278), remains November 1, 2015. Written comments must be submitted on or before November 12, 2015.

**FOR FURTHER INFORMATION CONTACT:** Robert Altneu, Chief, Trade and Commercial Regulations Branch, Regulations and Rulings, Office of International Trade, at [robert.f.altneu@cbp.dhs.gov](mailto:robert.f.altneu@cbp.dhs.gov).

**SUPPLEMENTARY INFORMATION:** On October 13, 2015, U.S. Customs and Border Protection (CBP) published in the **Federal Register** (80 FR 61278) an Interim Final Rule (CBP Dec. 15–14) document, entitled Automated Commercial Environment (ACE) Filings for Electronic Entry/Entry Summary (Cargo Release and Related Entry). As published, the Interim Final regulation contains an error in the text of Amendatory Instruction 38 in the “Amendments to the CBP Regulations” section of FR Doc. 2015–25729.

### Correction

On page 61289, in the second column, under “§ 141.57 [Amended]” revise Amendatory Instruction 38 to read as follows:

■ 38. Amend § 141.57, in paragraph (d)(2) by removing the words “through the Customs ACS (Automated Commercial System)” and adding in their place the words “to the CBP Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system”.

Dated: October 20, 2015.

**Harold M. Singer,**

*Director, Regulations and Disclosure Law Division, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection.*

**Heidi Cohen,**

*Senior Counsel for Regulatory Affairs, Department of the Treasury.*

[FR Doc. 2015–27103 Filed 10–23–15; 8:45 am]

**BILLING CODE 9111–14–P**

## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

#### 29 CFR Part 2509

RIN 1210–AB73

### Interpretive Bulletin Relating to the Fiduciary Standard Under ERISA in Considering Economically Targeted Investments

**AGENCY:** Employee Benefits Security Administration, Labor.

**ACTION:** Interpretive bulletin.

**SUMMARY:** This document sets forth supplemental views of the Department of Labor (Department) concerning the legal standard imposed by sections 403 and 404 of Part 4 of Title I of the Employee Retirement Income Security Act of 1974 (ERISA) with respect to a plan fiduciary’s decision to invest plan assets in “economically targeted investments” (ETIs). ETIs are generally defined as investments that are selected for the economic benefits they create in addition to the investment return to the employee benefit plan investor. In this document, the Department withdraws Interpretive Bulletin 08–01 and replaces it with Interpretive Bulletin 2015–01 that reinstates the language of Interpretive Bulletin 94–01.

**DATES:** This interpretive bulletin is effective on October 26, 2015.

**FOR FURTHER INFORMATION CONTACT:** Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500. This is not a toll-free number.

#### SUPPLEMENTARY INFORMATION:

#### Background

The Department has been asked periodically over the last 30 years to consider the application of ERISA’s fiduciary rules to pension plan investments selected because of the collateral economic or social benefits they may further in addition to their investment returns. Various terms have been used to describe this and related investment behaviors, such as socially responsible investing, sustainable and responsible investing, environmental, social and governance (ESG) investing, impact investing, and economically targeted investing (ETI). The terms do not have a uniform meaning and the terminology is evolving. As used in this interpretive bulletin, however, an economically targeted investment broadly refers to any investment that is selected, in part, for its collateral benefits, apart from the investment

return to the employee benefit plan investor. The Labor Department previously addressed issues relating to ETIs in Interpretive Bulletin 94–1 (IB 94–1)<sup>1</sup> and Interpretive Bulletin 2008–1 (IB 2008–1).<sup>2</sup> The Department’s stated objective in issuing IB 94–1 was to correct a popular misperception at the time that investments in ETIs are incompatible with ERISA’s fiduciary obligations. The preamble to the Interpretive Bulletin explained that the requirements of sections 403 and 404 of ERISA do not prevent plan fiduciaries from investing plan assets in ETIs if the ETI has an expected rate of return that is commensurate to rates of return of alternative investments with similar risk characteristics that are available to the plan, and if the ETI is otherwise an appropriate investment for the plan in terms of such factors as diversification and the investment policy of the plan. Some commenters have referred to this standard as the “all things being equal” test.

The Department has also consistently stated, including in Interpretive Bulletin 94–1, that the focus of plan fiduciaries on the plan’s financial returns and risk to beneficiaries must be paramount. Under ERISA, the plan trustee or other investing fiduciary may not use plan assets to promote social, environmental, or other public policy causes at the expense of the financial interests of the plan’s participants and beneficiaries. Fiduciaries may not accept lower expected returns or take on

<sup>1</sup> 59 FR 32606 (June 23, 1994). Prior to issuing IB 94–1, the Department had issued a number of letters concerning a fiduciary’s ability to consider the collateral effects of an investment and granted a variety of prohibited transaction exemptions to both individual plans and pooled investment vehicles involving investments, which produce collateral benefits. See, Advisory Opinions 80–33A, 85–36A and 88–16A; Information Letters to Mr. George Cox, dated January 16, 1981; to Mr. Theodore Groom, dated January 16, 1981; to The Trustees of the Twin City Carpenters and Joiners Pension Plan, dated May 19, 1981; to Mr. William Chadwick, dated July 21, 1982; to Mr. Daniel O’Sullivan, dated August 2, 1982; to Mr. Ralph Katz, dated March 15, 1982; to Mr. William Ecklund, dated December 18, 1985, and January 16, 1986; to Mr. Reed Larson, dated July 14, 1986; to Mr. James Ray, dated July 8, 1988; to the Honorable Jack Kemp, dated November 23, 1990; and to Mr. Stuart Cohen, dated May 14, 1993; PTE 76–1, part B, concerning construction loans by multiemployer plans; PTE 84–25, issued to the Pacific Coast Roofers Pension Plan; PTE 85–58, issued to the Northwestern Ohio Building Trades and Employer Construction Industry Investment Plan; PTE 87–20, issued to the Racine Construction Industry Pension Fund; PTE 87–70, issued to the Dayton Area Building and Construction Industry Investment Plan, PTE 88–96, issued to the Real Estate for American Labor A Balcor Group Trust; PTE 89–37, issued to the Union Bank; PTE 93–16, issued to the Toledo Roofers Local No. 134 Pension Plan and Trust, et al.

<sup>2</sup> 73 FR 61734 (October 17, 2008).

greater risks in order to secure collateral benefits.

Specifically, the Department stated in Interpretive Bulletin 94–1:<sup>3</sup>

Sections 403 and 404 of the Employee Retirement Income Security Act of 1974 (ERISA), in part, require that a fiduciary of a plan act prudently, and to diversify plan investments so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so. In addition, these sections require that a fiduciary act solely in the interest of the plan's participants and beneficiaries and for the exclusive purpose of providing benefits to their participants and beneficiaries. The Department has construed the requirements that a fiduciary act solely in the interest of, and for the exclusive purpose of providing benefits to, participants and beneficiaries as prohibiting a fiduciary from subordinating the interests of participants and beneficiaries in their retirement income to unrelated objectives.

The Department continued in Interpretive Bulletin 2008–1:<sup>4</sup>

ERISA's plain text thus establishes a clear rule that in the course of discharging their duties, fiduciaries may never subordinate the economic interests of the plan [participants and beneficiaries] to unrelated objectives [ ].

In the preamble to IB 94–1, the Department elaborated:<sup>5</sup>

While the Department has stated that a plan fiduciary may consider collateral benefits in choosing between investments that have comparable risks and rates of return, it has consistently held that fiduciaries who are willing to accept expected reduced returns or greater risks to secure collateral benefits are in violation of ERISA. It follows that, because every investment necessarily causes a plan to forgo other investment opportunities, an investment will not be prudent if it would provide a plan with a lower expected rate of return than available alternative investments with commensurate degrees of risk or is riskier than alternative available investments with commensurate rates of return.

Thus, it has been the Department's consistent view that sections 403 and 404 of ERISA do not permit fiduciaries to sacrifice the economic interests of plan participants in receiving their promised benefits in order to promote collateral goals.

At the same time, however, the Department has consistently recognized that fiduciaries may consider such collateral goals as tie-breakers when choosing between investment alternatives that are otherwise equal with respect to return and risk over the appropriate time horizon. ERISA does not direct an investment choice in circumstances where investment

alternatives are equivalent, and the economic interests of the plan's participants and beneficiaries are protected if the selected investment is in fact, economically equivalent to competing investments.

On October 17, 2008, the Department replaced Interpretive Bulletin 94–1, with Interpretive Bulletin 2008–01, codified at 29 CFR 2509.08–01. IB 2008–01 purported not to alter the basic legal principles set forth in IB 94–1. Its stated purpose was to clarify that fiduciary consideration of collateral, non-economic factors in selecting plan investments should be rare and, when considered, should be documented in a manner that demonstrates compliance with ERISA's rigorous fiduciary standards.

The Department believes that in the seven years since its publication, IB 2008–01 has unduly discouraged fiduciaries from considering ETIs and ESG factors. In particular, the Department is concerned that the 2008 guidance may be dissuading fiduciaries from (1) pursuing investment strategies that consider environmental, social, and governance factors, even where they are used solely to evaluate the economic benefits of investments and identify economically superior investments, and (2) investing in ETIs even where economically equivalent. Some fiduciaries believe the 2008 guidance sets a higher but unclear standard of compliance for fiduciaries when they are considering ESG factors or ETI investments.

An important purpose of this Interpretive Bulletin is to clarify that plan fiduciaries should appropriately consider factors that potentially influence risk and return. Environmental, social, and governance issues may have a direct relationship to the economic value of the plan's investment. In these instances, such issues are not merely collateral considerations or tie-breakers, but rather are proper components of the fiduciary's primary analysis of the economic merits of competing investment choices. Similarly, if a fiduciary prudently determines that an investment is appropriate based solely on economic considerations, including those that may derive from environmental, social and governance factors, the fiduciary may make the investment without regard to any collateral benefits the investment may also promote. Fiduciaries need not treat commercially reasonable investments as inherently suspect or in need of special scrutiny merely because they take into consideration environmental, social, or other such factors. When a fiduciary

prudently concludes that such an investment is justified based solely on the economic merits of the investment, there is no need to evaluate collateral goals as tie-breakers.

In addition, this Interpretive Bulletin also clarifies that plan fiduciaries may invest in ETIs based, in part, on their collateral benefits so long as the investment is economically equivalent, with respect to return and risk to beneficiaries in the appropriate time horizon, to investments without such collateral benefits. In an effort to correct the misperceptions that have followed publication of IB 2008–01 the Department is withdrawing IB 2008–01, replacing it with this guidance that reinstates the language of IB 94–1.

Consistent with fiduciaries' obligations to choose economically superior investments, the Department does not believe ERISA prohibits a fiduciary from addressing ETIs or incorporating ESG factors in investment policy statements or integrating ESG-related tools, metrics and analyses to evaluate an investment's risk or return or choose among otherwise equivalent investments. Nor do sections 403 and 404 prevent fiduciaries from considering whether and how potential investment managers consider ETIs or use ESG criteria in their investment practices. As in selecting investments, in selecting investment managers, the plan fiduciaries must reasonably conclude that the investment manager's practices in selecting investments are consistent with the principles articulated in this guidance.

In addition, the Department does not construe consideration of ETIs or ESG criteria as presumptively requiring additional documentation or evaluation beyond that required by fiduciary standards applicable to plan investments generally. As a general matter, the Department believes that fiduciaries responsible for investing plan assets should maintain records sufficient to demonstrate compliance with ERISA's fiduciary provisions. As with any other investments, the appropriate level of documentation would depend on the facts and circumstances.

The Department also has concluded that the same standards set forth in sections 403 and 404 of ERISA governing a fiduciary's investment decisions, discussed above, apply to a fiduciary's selection of a "socially-responsible" mutual fund as a plan investment or, in the case of an ERISA section 404(c) plan or other individual account plan, a designated investment alternative under the plan. Specifically, in Advisory Opinion 98–04A, the

<sup>3</sup> 59 FR 32606, 07.

<sup>4</sup> 73 FR 61734, 35.

<sup>5</sup> 59 FR 32606, 07 (footnote omitted).

Department has expressed the view that the fiduciary standards of sections 403 and 404 do not preclude consideration of collateral benefits, such as those offered by a “socially-responsible” fund, in a fiduciary’s decision to designate an investment alternative in an individual account plan. Whether a particular fund or investment alternative satisfies the requirements set forth in sections 403 and 404 of ERISA is an inherently factual question that the appropriate plan fiduciaries must decide based on all the facts and circumstances of the individual situation.

The following Interpretive Bulletin deals solely with the applicability of the prudence and exclusive purpose requirements of ERISA as applied to fiduciary decisions to invest plan assets in ETIs, and in particular the collateral benefits they may provide apart from a plan’s performance and the interests of participants and beneficiaries in their retirement income. The bulletin does not supersede the regulatory standard contained at 29 CFR 2550.404a-1, nor does it address any issues which may arise in connection with the prohibited transaction provisions or the statutory exemptions from those provisions.

#### List of Subjects in 29 CFR Part 2509

Employee benefit plans, Pensions.

For the reasons set forth in the preamble, the Department is amending subchapter A, part 2509 of title 29 of the Code of Federal Regulations as follows:

#### SUBCHAPTER A—GENERAL

#### PART 2509—INTERPRETIVE BULLETINS RELATING TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

■ 1. The authority citation for part 2509 continues to read as follows:

**Authority:** 29 U.S.C. 1135. Secretary of Labor’s Order 1–2003, 68 FR 5374 (Feb. 3, 2003). Sections 2509.75–10 and 2509.75–2 issued under 29 U.S.C. 1052, 1053, 1054. Sec. 2509.75–5 also issued under 29 U.S.C. 1002. Sec. 2509.95–1 also issued under sec. 625, Public Law 109–280, 120 Stat. 780.

#### § 2509.08–1 [Removed]

■ 2. Part 2509 is amended by removing § 2509.08–1.

■ 3. Part 2509 is further amended by adding § 2509.2015–01 to read as follows:

#### § 2509.2015–01 Interpretive bulletin relating to the fiduciary standard under ERISA in considering economically targeted investments.

This Interpretive Bulletin sets forth the Department of Labor’s interpretation of sections 403 and 404 of the Employee

Retirement Income Security Act of 1974 (ERISA), as applied to employee benefit plan investments in “economically targeted investments” (ETIs), that is, investments selected for the economic benefits they create apart from their investment return to the employee benefit plan. Sections 403 and 404, in part, require that a fiduciary of a plan act prudently, and to diversify plan investments so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so. In addition, these sections require that a fiduciary act solely in the interest of the plan’s participants and beneficiaries and for the exclusive purpose of providing benefits to their participants and beneficiaries. The Department has construed the requirements that a fiduciary act solely in the interest of, and for the exclusive purpose of providing benefits to, participants and beneficiaries as prohibiting a fiduciary from subordinating the interests of participants and beneficiaries in their retirement income to unrelated objectives.

With regard to investing plan assets, the Department has issued a regulation, at 29 CFR 2550.404a–1, interpreting the prudence requirements of ERISA as they apply to the investment duties of fiduciaries of employee benefit plans. The regulation provides that the prudence requirements of section 404(a)(1)(B) are satisfied if (1) the fiduciary making an investment or engaging in an investment course of action has given appropriate consideration to those facts and circumstances that, given the scope of the fiduciary’s investment duties, the fiduciary knows or should know are relevant, and (2) the fiduciary acts accordingly. This includes giving appropriate consideration to the role that the investment or investment course of action plays (in terms of such factors as diversification, liquidity, and risk/return characteristics) with respect to that portion of the plan’s investment portfolio within the scope of the fiduciary’s responsibility.

Other facts and circumstances relevant to an investment or investment course of action would, in the view of the Department, include consideration of the expected return on alternative investments with similar risks available to the plan. It follows that, because every investment necessarily causes a plan to forgo other investment opportunities, an investment will not be prudent if it would be expected to provide a plan with a lower rate of return than available alternative investments with commensurate degrees

of risk or is riskier than alternative available investments with commensurate rates of return.

The fiduciary standards applicable to ETIs are no different than the standards applicable to plan investments generally. Therefore, if the above requirements are met, the selection of an ETI, or the engaging in an investment course of action intended to result in the selection of ETIs, will not violate section 404(a)(1)(A) and (B) and the exclusive purpose requirements of section 403.

**Phyllis C. Borzi,**

*Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.*

[FR Doc. 2015–27146 Filed 10–22–15; 11:15 am]

**BILLING CODE 4510–29–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[USCG–2015–0964]

#### Drawbridge Operation Regulations; Tchefuncta River, Madisonville, LA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from regulations.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the SR 22 Bridge over the Tchefuncta River, mile 2.5, at Madisonville, St. Tammany Parish, Louisiana. This deviation is necessary to complete scheduled maintenance of the bridge. This deviation allows the bridge to remain closed to navigation for approximately six weeks while allowing for two scheduled openings on scheduled work days except for a five-day period and a 36-hour period, both in December, when there will be complete closures. The bridge will operate normally on non-scheduled work days and on weekends.

**DATES:** This deviation is effective from 7 a.m. on November 2, 2015 until 7 p.m. on December 15, 2015.

**ADDRESSES:** The docket for this deviation, [USCG–2015–0964] is available at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Jim Wetherington, D8 Bridge Administration Branch, Coast Guard; telephone 504–671–2128, email [james.r.wetherington@uscg.mil](mailto:james.r.wetherington@uscg.mil).



**SUPPLEMENTARY INFORMATION:** Coastal Bridge Company, LLC, on behalf of Louisiana Department of Transportation and Development (LDOTD), requested a deviation from the operating regulation for the SR 22 Bridge across the Tchefuncta River, mile 2.5, at Madisonville, St. Tammany Parish, Louisiana. The SR 22 Bridge is a swing bridge with a vertical clearance of 6.2 feet above Mean High Water (MHW) in the closed-to-navigation position and unlimited clearance in the open-to-navigation position. The operation of this bridge is currently governed by 33 CFR 117.500.

The closure is necessary for mechanical and electrical rehabilitation of the bridge. The deviation from the operating regulations will be in effect from Monday, November 2, 2015 until Tuesday, December 15, 2015, except for weekends. Within this time frame there will be multiple closure periods, deviating from the regular operating schedule, as follows:

(1) The first closure period will be from 7 a.m. on November 9th, until 7 p.m. on November 13th, 2015, except that the bridge will open at 9 a.m. and 7 p.m., daily, to pass all vessel traffic;

(2) The second closure period will be from 7 a.m. on November 16th until 9 p.m. on November 17th except that the bridge will open at 9 a.m. and 7 p.m., daily, to pass all vessel traffic;

(3) The third closure period will be from 7 a.m. on November 23rd until 9 p.m. on November 24th except that the bridge will open at 9 a.m. and 7 p.m., daily, to pass all vessel traffic;

(4) The fourth closure period will be a total closure from 7 a.m. on November 30th until 7 p.m. on December 4th; there will be no openings during this period;

(5) The fifth and final closure period will be a total closure from 9 a.m. on December 14th until 7 p.m. on December 15th; there will be no openings during this period. All work is expected to be completed by 7 p.m. on Tuesday, December 15, 2015.

Any changes to the scheduled closure times will be announced through the Local Notice to Mariners or through a broadcast. The traffic on the Tchefuncta River is primarily recreational with minimal commercial traffic. The contractor approached each marina and business that could possibly be impacted and forwarded them a copy of the work schedule. No negative comments were noted.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass. The

Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time periods. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: October 20, 2015.

**David M. Frank,**

*Bridge Administrator, Eighth Coast Guard District.*

[FR Doc. 2015-27131 Filed 10-23-15; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2015-0904]

RIN 1625-AA09

#### **Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, John F. Kennedy Space Center/NASA Parkway Bridge, Addison Point, FL**

**ACTION:** Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the John F. Kennedy Space Center/NASA Parkway Bridge across the Atlantic Intracoastal Waterway, mile 885.0, Addison Point, FL. For the safety of the participants, this temporary operating schedule will allow the bridge to not open to navigation including tugs with tows, during the Rocketman Triathlon in November.

**DATES:** This deviation is effective from 7:30 a.m. on November 15, 2015 through 3 p.m. November 15, 2015.

**ADDRESSES:** The docket for this deviation, [USCG-2015-0904] is available at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this temporary deviation, call or email LT Storm, Coast Guard Sector Jacksonville, Chief, Prevention Office; telephone 904-564-7563, email [Allan.h.storm@uscg.mil](mailto:Allan.h.storm@uscg.mil).

**SUPPLEMENTARY INFORMATION:** In order to accommodate the annual Triathlon, a temporary schedule deviation has been authorized for the John F. Kennedy Space Center (NASA) Parkway Bridge,

across the Atlantic Intracoastal Waterway, mile 885.0 at Addison Point, FL. This deviation is in effect from 7:30 a.m. to 3 p.m. on November 15, 2015. During this time, the bridge shall remain closed to navigation, including tugs with tows. Currently, the bridge opens as required per 33 CFR 117.261(l). The regulation changes may have a minor impact on vessels transiting the Atlantic Intracoastal Waterway in the vicinity of Addison Point, FL, but will still meet the reasonable needs of navigation.

The John F. Kennedy Space Center (NASA) Parkway Bridge provides a vertical clearance of 27 feet at mean high water in the closed position and a horizontal clearance of 90 feet. Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will be able to open for emergencies. The Coast Guard will inform users of the waterways through Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately following the end of the effective period of this temporary deviation. This deviation from the normal operating regulations is authorized under 33 CFR 117.35.

Dated: 21 October 2015.

**Barry Dragon,**

*Director, Bridge Administration, Seventh Coast Guard District.*

[FR Doc. 2015-27115 Filed 10-23-15; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2015-0970]

#### **Drawbridge Operation Regulation; Houma Navigation Canal, Mile 36.0, at Houma, Terrebonne Parish, LA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the SR 661 Swing Bridge across the Houma Navigation Canal, mile 36.0, in Houma, Terrebonne Parish, Louisiana. The deviation is necessary to conduct scheduled metal repairs and maintenance. This deviation allows the bridge to remain closed-to-

navigation for up to six daylight hours each weekday for two weeks.

**DATES:** This deviation is effective from 6 a.m. on November 9, 2015, until 6 p.m. on November 20, 2015.

**ADDRESSES:** The docket for this deviation, [USCG–2015–0970] is available at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Jim Wetherington, Bridge Administration Branch, Coast Guard, telephone (504)671–2128, email [james.r.wetherington@uscg.mil](mailto:james.r.wetherington@uscg.mil).

**SUPPLEMENTARY INFORMATION:** C.E.C., Inc., for the Louisiana Department of Transportation and Development (LDOTD), requested a temporary deviation from the operating schedule of the SR 661 Swing Bridge across the Houma Navigation Canal, mile 36.0, in Houma, Terrebonne Parish, Louisiana. The vertical clearance of the swing bridge is one foot above mean high water in the closed-to-navigation position and unlimited in the open-to-navigation position. The bridge is governed by 33 CFR 117.455.

This deviation will be in effect from 6 a.m. through 6 p.m., daily, from November 9, 2015, until November 20, 2015 except weekends. This Deviation allows the bridge to remain closed-to-navigation for up to six hours, from 6 a.m. through 6 p.m. daily. During the evening and weekend time periods, the bridge will be left in the open-to-navigation position. During the closure periods, the contractor will make every effort to minimize the delays to mariners as well as maintain the bridge in the open-to-navigation position at all times when that repair work is not being conducted. Marine traffic, when allowed to pass, should pass at the slowest safe speed. The deviation was requested for the purpose of conducting necessary repairs and maintenance, including metal structure and rivet repair.

Navigation on the waterway consists primarily of commercial tugs and recreational craft. The contractor has informed the waterway users of the upcoming delays. This deviation is similar to previous work schedules and no issues were noted.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at anytime. The bridge will be able to open for emergencies, and there is no immediate alternate route. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that

vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: October 20, 2015.

**David M. Frank,**

*Bridge Administrator, Eighth Coast Guard District.*

[FR Doc. 2015–27130 Filed 10–23–15; 8:45 am]

**BILLING CODE 9110–04–P**

## POSTAL SERVICE

### 39 CFR Part 20

#### International Product and Price Changes

**AGENCY:** Postal Service™.

**ACTION:** Final rule.

**SUMMARY:** The Postal Service is revising *Mailing Standards of the United States Postal Service*, International Mail Manual (IMM®), to reflect the prices, product features, and classification changes to Competitive Services, as established by the Governors of the Postal Service.

**DATES:** *Effective date:* January 17, 2016.

**FOR FURTHER INFORMATION CONTACT:** Paula Rabkin at 202–268–2537.

**SUPPLEMENTARY INFORMATION:** New prices will be posted under Docket Number CP2016–9 on the Postal Regulatory Commission's Web site at <http://www.prc.gov>.

This final rule describes the international price and classification changes and the corresponding mailing standards changes for the following Competitive Services:

- Global Express Guaranteed® (GXG®).
- Priority Mail Express International™.
- Priority Mail International®.
- First-Class Package International Service™.
- International Priority Airmail® (IPA®).
- International Surface Air Lift® (ISAL®).
- Direct Sacks of Printed Matter to One Addressee (Airmail M-bags).
- International Extra Services:
- Insurance.
- International Postal Money Orders.
- International Money Order Inquiry Fee.
- International Money Transfer Service.

New prices will be located on the Postal Explorer® Web site at <http://pe.usps.com>.

#### Global Express Guaranteed

Global Express Guaranteed (GXG) is the Postal Service's premier international expedited product provided through an alliance with FedEx Express®. The price increase for GXG service averages 7.1 percent.

The Postal Service provides Commercial Base pricing to online customers who prepare and pay for GXG shipments via USPS-approved payment methods (with the exception of Click-N-Ship® service), with a 5 percent discount off the published retail prices for GXG. Customers who prepare GXG shipments via Click-N-Ship service will now pay retail prices.

The Postal Service continues to offer Commercial Plus pricing for large volume customers who commit to tendering \$100,000 in annual postal revenue from GXG, Priority Mail Express International, Priority Mail International, and First-Class Package International Service via USPS-approved payment methods. The Postal Service will also continue to include GXG in customized Global Expedited Package Services (GEPS) contracts offered to customers who meet certain revenue thresholds and are willing to commit a larger amount of revenue in international postage.

#### Priority Mail Express International

Priority Mail Express International (PMEI) service provides fast service to approximately 180 countries. Priority Mail Express International with Money-Back Guarantee service is available for certain destinations. The price increase for Priority Mail Express International service averages 11.6 percent. The Commercial Base price for customers that prepare and pay for Priority Mail Express International shipments via permit imprint, online at USPS.com®, or as registered end-users using an authorized PC Postage vendor (with the exception of Click-N-Ship service) will be 5 percent below the retail price. Customers who prepare Priority Mail Express International shipments via Click-N-Ship service will now pay retail prices. The Postal Service continues to offer Priority Mail Express International Commercial Plus pricing to large volume customers who commit to tendering \$100,000 in annual postal revenues from GXG, Priority Mail Express International, Priority Mail International, and First-Class Package International Service. The Postal Service will also continue to include Priority Mail Express International in

customized Global Expedited Package Services (GEPS) contracts offered to customers who meet certain revenue thresholds and are willing to commit a larger amount of revenue in international postage.

We are discontinuing the Priority Mail Express International Flat Rate Box. Customers who present items at retail to be mailed in a Priority Mail Express International Flat Rate Box will pay the retail price based on the item's weight and price group.

Priority Mail Express International flat rate pricing continues to be available for Flat Rate Envelopes. New this year, the prices for what was formerly the "all other countries" rate group are being replaced with flat rate prices in seven rate groups, based on geographical regions.

#### **Priority Mail International**

Priority Mail International (PMI) is an economical way to send merchandise and documents to about 180 countries. The price increase for Priority Mail International service averages 10.2 percent. The Commercial Base price for customers that prepare and pay for PMI items via permit imprint, online at USPS.com, or as registered end-users using an authorized PC Postage vendor (with the exception of Click-N-Ship service) will be 5 percent below the retail price. Customers who prepare Priority Mail International shipments via Click-N-Ship service will now pay retail prices. The Postal Service continues to offer Priority Mail International Commercial Plus pricing to large volume customers who commit to tendering \$100,000 in annual postal revenues from GXG, Priority Mail Express International, Priority Mail International, and First-Class Package International Service. The Postal Service will continue to include Priority Mail International in customized Global Expedited Package Services (GEPS) contracts offered to customers who meet certain revenue thresholds and are willing to commit to a larger amount of revenue to the USPS® for Priority Mail Express International and Priority Mail International.

Priority Mail International flat rate pricing continues to be available for Flat Rate Envelopes, Small Flat Rate Priced Boxes, and Medium and Large Flat Rate Boxes. New this year, the prices for what was formerly the "all other countries" rate group are being replaced with flat rate prices in seven rate groups, based on geographical regions.

In this filing, we are proposing a structural change in the way insurance is provided and reimbursed for Priority Mail International. Priority Mail

International shipments containing merchandise (other than in Priority Mail International Small Flat Rate Priced Boxes and Flat Rate Envelopes) will now be insured against loss, damage, or missing contents up to \$200 at no additional charge. Additional insurance coverage up to a maximum of \$5,000 (depending on individual country insurance limits) may be purchased at the sender's option. Priority Mail International shipments containing nonnegotiable documents (other than in Priority Mail International Flat Rate Envelopes and Small Flat Rate Priced Boxes) will now be insured against loss, damage, or missing contents up to \$100 for document reconstruction at no additional charge. The insurance coverage will be provided on all outbound Priority Mail International shipments accepted at retail or paid for by using postage validation imprinter (PVI) labels, postage meter imprints, USPS-approved PC Postage, Click-N-Ship service postage, or permit imprint.

Electronic USPS Delivery Confirmation International service—abbreviated E-USPS DELCON INTL—is an optional service available for Priority Mail International Flat Rate Envelopes (except for the Gift Card Flat Rate Envelope) and all Small Flat Rate Priced Boxes to select destination countries, for customers using select software or online tools, at no charge. We are adding E-USPS DELCON INTL service to four countries with this price change: Lebanon, Norway, Slovak Republic, and Turkey.

In the May 2015 price change, we created new price zones for Priority Mail International to Canada, based on the distance of the origin ZIP Code to the serving International Service Center (ISC). An ISC Zone Chart is now available for a subscription fee from the National Customer Support Center in Memphis, Tennessee, to support zone-based pricing for Priority Mail International to Canada. The chart will enable mailers to determine the applicable zone, based on the origin ZIP Code. Once the zone and weight of the item are known, the mailer will be able to determine the applicable postage price.

#### **First-Class Package International Service**

First-Class Package International Service (FCPIS) is an economical international service for small packages weighing less than 4 pounds and not exceeding \$400 in value. The pricing structure for FCPIS will continue to be simpler than for some other international products, with identical prices for 0 to 8 ounces within each

country price group, and identical prices for 9 to 32 ounces within each country price group. The price increase for FCPIS averages 21.6 percent. The Commercial Base price for customers that prepare and pay for FCPIS items via permit imprint or by USPS-approved online payment methods will be 5 percent below the retail price. Customers who prepare First-Class Package International Service shipments via Click-N-Ship service will now pay retail prices. Commercial Plus pricing will be available to large volume customers who commit to tendering \$100,000 in annual postal revenue for GXG, Priority Mail Express International, Priority Mail International, and First-Class Package International Service.

Electronic USPS Delivery Confirmation International service—abbreviated E-USPS DELCON INTL—is an optional service available for First-Class Package International Service items to select destination countries, for customers using select software or online tools, at no charge. We are adding E-USPS DELCON INTL service to four countries with this price change: Lebanon, Norway, Slovak Republic, and Turkey.

#### **International Priority Airmail and International Surface Air Lift**

Published prices for International Priority Airmail (IPA) and International Surface Air Lift (ISAL) will increase by 4.2 percent for IPA and 3.5 percent for IPA M-bags, as well as 6.3 percent for ISAL and 5.3 percent for ISAL M-bags. The structure of IPA and ISAL price categories will continue to be priced by the worldwide and 19 country price groups and applicable mail shapes (letters and postcards, large envelopes [flats], and packages [small packets and rolls]). These categories correspond to the Universal Postal Convention requirements to use shape-based pricing. For IPA and ISAL, the Postal Service offers incentive pricing through International Negotiated Service Agreements (NSAs).

International Priority Airmail (IPA) service, including IPA M-bags, is a bulk commercial service that provides business mailers with rapid and economical worldwide delivery for volume mailings of First-Class Mail International postcards, letters, large envelopes (flats), and FCPIS packages (small packets) weighing up to a maximum 4.4 pounds. IPA is dispatched to the destination country where it is entered into the postal administration's air or surface priority mail system for delivery. The overall

price increase for IPA service averages 4.2 percent.

International Surface Air Lift (ISAL) service, including ISAL M-bags, is a bulk commercial service that provides economical worldwide delivery to business mailers of volume mailings of all First-Class Mail International postcards, letters, large envelopes (flats), and FCPIIS packages (small packets) weighing up to 4.4 pounds. ISAL is dispatched to the destination country where it is then entered into the postal administration's surface nonpriority network for delivery. The overall price increase for ISAL service averages 6 percent.

**Direct Sacks of Printed Matter to One Addressee (Airmail M-Bags)**

Airmail M-bags are direct sacks of printed matter sent to a single foreign addressee at a single address. Prices are based on the weight of the sack. The price increase for Airmail M-bags averages 9.2 percent.

**International Extra Services and Fees**

Depending on country destination and mail type, customers may add a variety of extra services to their outbound shipments. Prices for some of these extra services are increasing:

- *International Postal Money Orders* will increase 5.6 percent.
- *International Money Order Inquiry Fee* will increase 3.5 percent.
- *International Money Transfer Service* will increase 3.3 to 3.7 percent, depending on the rate cell.

**List of Subjects in 39 CFR Part 20**

Foreign relations, International postal services.

The Postal Service hereby adopts the following changes to *Mailing Standards of the United States Postal Service, International Mail Manual (IMM)*, which is incorporated by reference in the *Code of Federal Regulations*. See 39 CFR 20.1.

Accordingly, 39 CFR part 20 is amended as follows:

**PART 20—[AMENDED]**

■ 1. The authority citation for 39 CFR part 20 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, 407, 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, International Mail Manual (IMM)*, as follows:

\* \* \* \* \*

**Mailing Standards of the United States Postal Service, International Mail Manual (IMM)**

\* \* \* \* \*

**1 International Mail Services**

\* \* \* \* \*

**130 Mailability**

\* \* \* \* \*

**134 Valuable Articles**

**134.1 Service Options**

*[Delete distinctions between Priority Mail International service with and without insurance as follows:]*

d. Priority Mail International service (except for Priority Mail International Small Flat Rate Priced Boxes and Flat Rate Envelopes).

**Note:** Priority Mail Express International service cannot be used to send the articles noted in 134.2.

\* \* \* \* \*

**2 Conditions for Mailing**

**210 Global Express Guaranteed**

\* \* \* \* \*

**213 Prices and Postage Payment Methods**

\* \* \* \* \*

**213.6 Commercial Prices**

\* \* \* \* \*

**213.62 Commercial Plus Prices**

**213.621 General**

*[Revise the first sentence to read as follows (eliminating the availability of Commercial Plus prices for users of Click-N-Ship service and eliminating the difference in price between Commercial Base and Commercial Plus prices):]*

An approved mailer who pays postage with a permit imprint under 213.8, or through a registered end-user of a USPS-approved PC Postage product (except for Click-N-Ship service), qualifies for the Global Express Guaranteed Commercial Plus prices. \* \* \*

\* \* \* \* \*

**213.7 Online Methods**

**213.71 Online Prices—Commercial Base or Commercial Plus Prices**

*[Revise the text to read as follows (eliminating the availability of Commercial Base and Commercial Plus prices for users of Click-N-Ship service):]*

For selected destination countries, Global Express Guaranteed items qualify for discounted prices (equal to the Commercial Base price or Commercial

Plus price) when mailers use one of the following online shipping methods:

a. Commercial Base Price: Registered end-users of USPS-approved PC Postage products using online postage (with the exception of Click-N-Ship service); or a USPS meter label solution using metered postage.

b. Commercial Plus Price: Registered end-users of USPS-approved PC Postage products (with the exception of Click-N-Ship service).

Commercial Base and Commercial Plus prices are not available through Click-N-Ship service. The Commercial Base or Commercial Plus price is automatically applied to each shipment when using one of the postage payment methods above. The discount applies only to the postage portion of the Global Express Guaranteed price. It does not apply to any other charges or fees, such as fees for Pickup on Demand service, insurance, or shipments made under a customized agreement.

\* \* \* \* \*

**220 Priority Mail Express International**

**221 Description and Physical Characteristics**

\* \* \* \* \*

**221.3 Priority Mail Express International Flat Rate Envelopes**

*[Revise the first sentence to read as follows (adding a reference to the rate group):]*

Only USPS-produced Priority Mail Express International Flat Rate Envelopes are eligible for the Flat Rate price and are charged a flat rate price depending on the rate group of the destination. \* \* \*

*[Delete 221.4 and renumber current 221.5 as 221.4 (there are no other changes except renumbering)]*

\* \* \* \* \*

**222 Eligibility**

\* \* \* \* \*

*[Delete 222.4, "Priority Mail Express International Flat Rate Boxes," in its entirety (including Exhibit 222.4), and renumber current 222.5 through 222.8 as 222.4 through 222.7 (there are no other changes except renumbering):]*

\* \* \* \* \*

**223 Prices and Postage Payment Methods**

**223.1 Prices**

**223.11 Availability and Price Application—General**

*[Delete reference to 223.15 to read as follows:]*

Except under 223.14, Priority Mail Express International shipments are

charged postage for each addressed piece according to its weight and country price group. \* \* \* \* \*

223.13 Commercial Plus Prices

[Revise 223.13 to read as follows:] An approved mailer who pays postage with a permit imprint under 223.222, or as a registered end-user of a USPS-approved PC Postage product (except for Click-N-Ship service), qualifies for the Priority Mail Express International Commercial Plus prices, which are the same as Priority Mail Express International Commercial Base prices. Customers who prepare Priority Mail Express International shipments via Click-N-Ship service pay retail prices. See Notice 123, Price List, for the applicable price.

[Delete 223.15 Priority Mail Express International Flat Rate Boxes Prices in its entirety]

223.2 Postage Payment Methods

223.24 Online Methods

223.241 Online Prices—Commercial Base or Commercial Plus Prices

[Revise the first paragraph to read as follows (eliminating the availability of Commercial Base and Commercial Plus prices for users of Click-N-Ship service):]

For selected destination countries, Priority Mail Express International items qualify for discounted prices (equal to the Commercial Base price or Commercial Plus price) when mailers use one of the following online shipping methods:

a. Commercial Base Price: Registered end-users of USPS-approved PC Postage products using online postage (with the exception of Click-N-Ship service) or a USPS meter label solution using metered postage.

b. Commercial Plus Price: Registered end-users of USPS-approved PC Postage products (with the exception of Click-N-Ship service).

230 Priority Mail International

232 Eligibility

232.1 Priority Mail International Flat Rate Envelopes and Small Flat Rate Priced Boxes

232.12 Electronic USPS Delivery Confirmation International

232.122 Availability

Exhibit 232.122

Countries Accepting Electronic USPS Delivery Confirmation International Service

Note: An asterisk indicates that service was temporarily suspended on June 12, 2014.

[Revise the exhibit to read as follows (adding Lebanon, Norway, Slovak Republic, and Turkey):]

- Australia
Belgium
Brazil\*
Canada
Croatia
Denmark\*
Estonia
Finland
France\*
Germany
Gibraltar\*
Great Britain and Northern Ireland
Hungary
Israel
Italy\*
Latvia
Lebanon
Lithuania
Luxembourg\*
Malaysia
Malta
Netherlands
New Zealand
Norway
Portugal\*
Singapore
Slovak Republic
Spain
Switzerland
Turkey

232.126 Price Eligibility

[Revise the text to read as follows (eliminating the availability of Commercial Base and Commercial Plus prices for users of Click-N-Ship service):]

Only items paid with USPS-approved PC Postage (with the exception of Click-N-Ship service), permit imprint, or a USPS meter label solution are eligible for the applicable Commercial Base or Commercial Plus price for the postage portion of the mailpiece. Customers using a USPS meter label solution to print shipping labels must apply postage from a meter to be eligible for Commercial Base or Commercial Plus prices. Items with electronically generated customs forms that are not generated with PC Postage, a permit imprint, or a USPS meter label solution (for example, forms electronically generated by Webtools or Click-N-Ship service) are charged the retail price.

232.5 Priority Mail International Parcels

232.51 General

[Replace the next-to-last sentence with the following two sentences to read as follows:]

\* \* \* Priority Mail International parcels containing merchandise are insured against loss, damage, or missing contents up to \$200 at no additional charge. Additional insurance may be available, depending on country and value—see Exhibit 322.2 and the Individual Country Listings for insurance availability, limitations, and coverage.

232.6 Customs Forms Required

[Revise the title and text of 232.63 to read as follows (removing references to ordinary and insured parcels):]

232.63 Priority Mail International Parcels

Each Priority Mail International parcel must bear a properly completed PS Form 2976-A.

232.8 Priority Mail International Insurance and Indemnity

232.81 Indemnity

[Revise the first two sentences to read as follows:]

Except for Small Flat Rate Priced Boxes, Priority Mail International parcels containing merchandise are insured against loss, damage, or missing contents up to \$200 at no additional charge. Indemnity is limited to the lesser of the actual value of the contents or \$200.

[Revise the Note to read as follows:]

Note: Merchandise insurance that provides coverage greater than the included \$200 merchandise insurance may be available, depending on country, content, and value—see Exhibit 322.2 and the Individual Country Listings for insurance availability, limitations, and coverage. When merchandise insurance is purchased, it replaces the included \$200 merchandise insurance.

232.82 Exclusions

[Revise the entire section to read as follows:]

Insurance coverage is not provided for consequential losses, delay, concealed damage, spoilage of perishable items, articles improperly packaged, articles too fragile to withstand normal handling in the mail, or prohibited articles.

[Delete 232.83 Ordinary Priority Mail International Weight and Indemnity Limits in its entirety (including Exhibit 232.83)]

**232.9 Extra Services**

**232.91 Certificate of Mailing**

*[Revise the text to read as follows:]*

Certificate of mailing service is available for purchase only for Priority Mail International Flat Rate Envelopes and Small Flat Rate Priced Boxes.

**232.92 Merchandise Insurance**

*[Revise the text to read as follows:]*

Merchandise insurance that provides coverage greater than the included \$200 merchandise insurance is available for Priority Mail International parcels, except Small Flat Rate Priced Boxes, to many countries. When merchandise insurance is purchased, it replaces the included \$200 merchandise insurance. See Exhibit 322.2 and the Individual Country Listings for insurance availability, limitations, and coverage. See Notice 123, *Price List*, for the fee schedule for Priority Mail International merchandise insurance coverage.

\* \* \* \* \*

**233 Prices and Postage Payment Methods**

**233.1 Prices**

**233.11 Availability and Price Application—General**

*[After the current text, add text to read as follows:]*

\* \* \* Price zones for Priority Mail International to Canada are based on the distance of the origin ZIP Code to the serving International Service Center (ISC). An ISC Zone Chart is available by subscription from the National Customer Support Center in Memphis. To purchase copies of the Zone Chart, call the Zone Chart program administrator at 800-238-3150 or write to the following address: NATIONAL CUSTOMER SUPPORT CENTER, UNITED STATES POSTAL SERVICE, 225 N HUMPHREYS BLVD STE 501, MEMPHIS TN 38188-1001.

\* \* \* \* \*

**233.13 Commercial Plus Prices**

*[Revise the first sentence to read as follows (eliminating the distinction between Commercial Base and Commercial Plus prices and excluding Click-N-Ship service):]*

An approved mailer who pays postage with a permit imprint under 233.222, or through a registered end-user of a USPS-approved PC Postage product (with the exception of Click-N-Ship service), qualifies for the Priority Mail International Commercial Plus prices.

\* \* \* \* \*

**233.14 Priority Mail International Flat Rate Envelopes and Small Flat Rate Priced Boxes**

*[Revise the first sentence to read as follows (adding a reference to the rate group):]*

Priority Mail International Flat Rate Envelopes and Small Flat Rate Priced Boxes are charged a flat rate price depending on the rate group of the destination. \* \* \*

**233.15 Priority Mail International Medium and Large Flat Rate Boxes**

*[Revise the first sentence to read as follows (adding a reference to the rate group):]*

The Priority Mail International Medium and Large Flat Rate Boxes are charged a flat rate price depending on the rate group of the destination. \* \* \*

\* \* \* \* \*

**233.2 Postage Payment Methods**

\* \* \* \* \*

**233.22. Permit Imprint**

\* \* \* \* \*

**233.222 Permit Imprint—Commercial Base or Commercial Plus**

*[Revise the first sentence of the text to read as follows (eliminating the distinction between Commercial Base and Commercial Plus prices):]*

A mailer who pays postage with a permit imprint qualifies for the Priority Mail International Commercial Base or Commercial Plus prices.

\* \* \* \* \*

**233.23 Online Methods**

**233.231 Online Prices—Commercial Base or Commercial Plus Prices**

*[Revise the first paragraph to read as follows (eliminating the availability of Commercial Base and Commercial Plus prices for users of Click-N-Ship service):]*

For selected destination countries, Priority Mail International items qualify for discounted prices (equal to the Commercial Base price or Commercial Plus price) when mailers use one of the following online shipping methods:

a. Commercial Base Price: Registered end-users of USPS-approved PC Postage products using online postage (with the exception of Click-N-Ship service); or a USPS meter label solution using metered postage.

b. Commercial Plus Price: Registered end-users of an authorized PC Postage vendor (with the exception of Click-N-Ship service).

\* \* \* \* \*

**250 First-Class Package International Service**

\* \* \* \* \*

**252 Eligibility**

\* \* \* \* \*

**252.2 Electronic USPS Delivery Confirmation International**

\* \* \* \* \*

**252.22 Availability**

\* \* \* \* \*

**Exhibit 252.22**

**Countries Accepting Electronic USPS Delivery Confirmation International Service**

**Note:** An asterisk indicates that service was temporarily suspended on June 12, 2014.

*[Revise the exhibit as follows, adding Lebanon, Norway, Slovak Republic, and Turkey:]*

- Australia
- Belgium
- Brazil\*
- Canada
- Croatia
- Denmark\*
- Estonia
- Finland
- France\*
- Germany
- Gibraltar\*
- Great Britain and Northern Ireland
- Hungary
- Israel
- Italy\*
- Latvia
- Lebanon
- Lithuania
- Luxembourg\*
- Malaysia
- Malta
- Netherlands
- New Zealand
- Norway
- Portugal\*
- Singapore
- Slovak Republic
- Spain
- Switzerland
- Turkey

**252.26 Price Eligibility**

*[Revise the text to read as follows (eliminating the availability of Commercial Base and Commercial Plus prices for users of Click-N-Ship service):]*

Only items paid with USPS-approved PC Postage (with the exception of Click-N-Ship service), permit imprint, or a USPS meter label solution are eligible for the applicable Commercial Base or Commercial Plus price for the postage

portion of the mailpiece. Customers using a USPS meter label solution to print shipping labels must apply postage from a meter to be eligible for Commercial Base or Commercial Plus prices. Electronically generated customs forms that are not generated with PC Postage (with the exception of Click-N-Ship service), a permit imprint, or a USPS meter label solution (for example, forms electronically generated by Webtools) are charged the retail price.

253 Prices and Postage Payment Methods

253.1 Prices

253.15 Commercial Plus Prices

[Revise the first sentence to read as follows (eliminating the distinction between Commercial Base and Commercial Plus prices and the availability of Commercial Plus Prices for users of Click-N-Ship service):]

An approved mailer who pays postage with a permit imprint under 253.222, or through a registered end-user of a USPS-approved PC Postage product (with the exception of Click-N-Ship service), qualifies for the First-Class Package International Service Commercial Plus prices.

253.2 Postage Payment Methods

253.23 Online Methods

253.231 Online Prices—Commercial Base or Commercial Plus Prices

[Revise the first paragraph to read as follows (eliminating the availability of Commercial Base and Commercial Plus Prices for users of Click-N-Ship service):]

For selected destination countries, First-Class Package International Service items qualify for discounted prices (equal to the Commercial Base price or Commercial Plus price) when mailers use one of the following online shipping methods:

a. Commercial Base Price: Registered end-users of USPS-approved PC Postage products (with the exception of Click-N-Ship service) using online postage; or a USPS meter label solution using metered postage.

b. Commercial Plus Price: Registered end-users of an authorized PC Postage vendor (with the exception of Click-N-Ship service).

3 Extra Services

310 Certificate of Mailing

311 Individual Pieces

311.2 Availability

311.21 At Time of Purchase

A customer may purchase a certificate of mailing (individual pieces) when sending the following:

[Delete item f and renumber item g as item f]

320 Insurance

323 Priority Mail International Insurance

323.1 Description

[Revise the text to read as follows:] Insurance is not available for Priority Mail International Flat Rate Envelopes or Small Flat Rate Priced Boxes. Priority Mail International shipments containing merchandise are insured against loss, damage, or missing contents up to \$200 at no additional charge. Priority Mail International shipments containing only nonnegotiable documents are insured against loss, damage, or missing contents up to \$100 for document reconstruction at no additional charge. Indemnity is paid by the U.S. Postal Service as provided in 933. For a fee, the sender may purchase additional insurance to protect against loss, damage, or missing contents for Priority Mail International parcels containing merchandise. Additional document reconstruction insurance may not be purchased. If the parcel has been lost, or if it has been delivered to the addressee in damaged condition or with missing contents, payment is made to the sender unless the sender waives the right to payment, in writing, in favor of the addressee.

323.2 Availability

[Revise first sentence to read as follows (including a reference to Medium and Large Flat Rate Boxes):]

Merchandise insurance above the included \$200 amount is available only for Priority Mail International parcels (including Medium and Large Flat Rate Boxes) and only to certain countries.

323.3 Coverage and Fees

[Revise the text to read as follows (adding references to additional merchandise insurance):]

Additional merchandise insurance coverage above the included \$200—up to the maximum amount allowed by the

country (see Exhibit 322.2) but never to exceed \$5,000—may be purchased at the sender's option. The insurance fee is in addition to postage and other applicable fees and is based on the insured value. See Notice 123, Price List, for the fee schedule for optional Priority Mail International merchandise insurance coverage.

323.6 Preparation of Insured Priority Mail International Parcels

323.62 Accepting Clerk's Responsibility

The accepting clerk must do the following: [Revise items a through c to read as follows and delete Exhibit 323.62 in its entirety:]

a. When additional insurance has been purchased, indicate on PS Form 2976-A the amount for which the parcel is insured. Write the amount in U.S. dollars in ink in the "Insured Amount (U.S. \$)" block.

b. When additional insurance has been purchased, as an indicator write a bold capital "V" in the space provided adjacent to the boxes for Insured Amount and Insurance Fees.

c. Round stamp PS Form 2976-A in the appropriate place on each copy.

9 Inquiries, Indemnities, and Refunds

930 Indemnity Payments

[Revise the title of 932 to read as follows (removing the distinction between insured and ordinary parcels):]

932 General Exceptions to Payment—Registered Mail and Priority Mail International Parcels

[Revise the title of 933 to read as follows (removing the distinction between insured and ordinary parcels):]

933 Payments for Priority Mail International Parcels

933.1 General Provisions

[Revise the title of 933.11 to read as follows (removing the reference to insured parcels):]

933.11 Payment of Indemnity

[Insert a new paragraph at the beginning of 933.11 to read as follows:] Priority Mail International shipments are covered by document reconstruction and merchandise insurance in case of loss, damage, or missing contents. Indemnity will be paid by the Postal

Service as specified in DMM 503.4 and 609, subject to the exclusions in IMM 933.12.

\* \* \* \* \*

[Revise the title of 933.13 to read as follows (removing the reference to ordinary parcels):]

**933.13 Priority Mail International Parcels—Indemnity Limitations**

[Revise the text to read as follows:]

When additional merchandise insurance has not been purchased, coverage is limited to the actual value of the contents or \$200, whichever is less. Document reconstruction insurance is limited to the actual cost of document reconstruction or \$100, whichever is less.

[Revise the title of 933.14 to read as follows (removing the reference to ordinary parcels):]

**933.14 Priority Mail International Parcels—Exceptions to Indemnity**

\* \* \* \* \*

**Country Price Groups and Weight Limits**

[Revise the text and table to read as follows (adding columns to Priority Mail Express International and Priority Mail International to show price groups for Flat Rate products; editing, combining, and reordering current footnotes, including removing a separate footnote for Cuba regarding conditions that can be found in Cuba’s Individual Country Listing and in Publication 699, Special Requirements for Shipping Internationally; and adding a new entry for Bonaire, Sint Eustatius, and Saba):]

Listed below are the countries and their price groups and weight limits for the five principal categories of international mail. Complete tables of prices are available in Notice 123, Price List.

n/a = Service is not available.

<sup>1</sup> Priority Mail Express International Flat Rate Envelopes maximum weight: 4 lbs.

<sup>2</sup> Priority Mail International Flat Rate Service maximum weights: Flat Rate Envelopes and Small Flat Rate Priced

Boxes, 4 lbs.; Medium and Large Flat Rate Boxes, 20 lbs.

<sup>3</sup> First-Class Mail International maximum weights: Letters, 3.5 ozs.; Large Envelopes (flats), 4 lbs. Note that the heading in the maximum weight column lists both ounces and pounds (“ozs./lbs.”) and that there are two numbers in the entry for each country (“3.5/4”)—this indicates that the maximum weight for Letters is 3.5 ozs., and that the maximum weight for Large Envelopes (flats) is 4 lbs. For First-Class Package International Service, the maximum weight is 4 lbs.

<sup>4</sup> Ascension, Bolivia, Cuba, and the Falkland Islands: Only Priority Mail International Flat Rate Envelopes and Small Flat Rate Priced Boxes (maximum weight: 4 lbs. each) may be used.

<sup>5</sup> Korea, Democratic People’s Republic of (North Korea): Only Priority Mail International Flat Rate Envelopes (maximum weight: 4 lbs.) may be used. Dutiable items and merchandise are prohibited.

Country	Global Express Guaranteed		Priority Mail Express International			Priority Mail International			First-Class Mail International and First-Class Package International Service	
	Price group	Max. wt. (lbs.)	Price group	Max. wt. (lbs.)	PMEI Flat Rate Envelopes price group <sup>1</sup>	Price group	Max. wt. (ozs./lbs.)	PMI Flat Rate Envelopes and Boxes price group <sup>2</sup>	Price group	Max. wt. (ozs./lbs.) <sup>3</sup>
Afghanistan .....	6	70	n/a	n/a	n/a	6	66	8	6	3.5/4
Albania .....	4	70	4	66	8	4	44	8	4	3.5/4
Algeria .....	4	70	8	44	8	8	44	8	8	3.5/4
Andorra .....	5	4	5	66	8	5	66	8	5	3.5/4
Angola .....	4	70	7	44	8	7	44	8	7	3.5/4
Anguilla .....	7	70	9	55	8	9	22	8	9	3.5/4
Antigua and Barbuda .....	7	70	n/a	n/a	n/a	9	22	8	9	3.5/4
Argentina .....	8	70	9	44	2	9	44	2	9	3.5/4
Armenia .....	4	70	4	44	8	4	44	8	4	3.5/4
Aruba .....	7	70	9	44	8	9	44	8	9	3.5/4
Ascension <sup>4</sup> .....	n/a	n/a	n/a	n/a	n/a	n/a	4	8	7	3.5/4
Australia .....	6	70	10	66	6	10	66	6	3	3.5/4
Austria .....	5	70	5	66	4	5	66	4	5	3.5/4
Azerbaijan .....	4	70	4	70	8	4	70	8	4	3.5/4
Bahamas .....	7	70	9	22	8	9	22	8	9	3.5/4
Bahrain .....	6	70	8	44	8	8	44	8	8	3.5/4
Bangladesh .....	6	70	6	44	8	6	44	8	6	3.5/4
Barbados .....	7	70	9	66	8	9	44	8	9	3.5/4
Belarus .....	4	70	4	44	8	4	66	8	4	3.5/4
Belgium .....	3	70	5	66	4	5	66	4	5	3.5/4
Belize .....	8	70	9	66	8	9	44	8	9	3.5/4
Benin .....	4	70	7	66	8	7	66	8	7	3.5/4
Bermuda .....	7	70	9	44	8	9	44	8	9	3.5/4
Bhutan .....	6	70	6	66	8	6	66	8	6	3.5/4
Bolivia <sup>4</sup> .....	8	70	9	66	2	n/a	4	2	9	3.5/4
Bonaire, Sint Eustatius, and Saba .....	7	70	9	66	8	9	44	8	9	3.5/4
Bosnia-Herzegovina .....	4	70	4	66	8	4	44	8	4	3.5/4
Botswana .....	4	70	7	66	8	7	66	8	7	3.5/4
Brazil .....	8	70	15	66	2	15	66	2	9	3.5/4
British Virgin Islands .....	7	70	n/a	n/a	n/a	9	44	8	9	3.5/4
Brunei Darussalam .....	4	70	6	66	8	6	44	8	6	3.5/4
Bulgaria .....	4	70	4	66	8	4	70	8	4	3.5/4
Burkina Faso .....	4	70	7	70	8	7	66	8	7	3.5/4
Burma (Myanmar) .....	n/a	n/a	6	44	8	6	22	8	6	3.5/4



Country	Global Express Guaranteed		Priority Mail Express International			Priority Mail International			First-Class Mail International and First-Class Package International Service	
	Price group	Max. wt. (lbs.)	Price group	Max. wt. (lbs.)	PMEI Flat Rate Envelopes price group <sup>1</sup>	Price group	Max. wt. (ozs./lbs.)	PMI Flat Rate Envelopes and Boxes price group <sup>2</sup>	Price group	Max. wt. (ozs./lbs.) <sup>3</sup>
Burundi .....	4	70	7	66	8	7	66	8	7	3.5/4
Cambodia (Kampuchea) .....	8	70	6	66	8	6	66	8	6	3.5/4
Cameroon .....	4	70	7	44	8	7	66	8	7	3.5/4
Canada .....	1	70	1	66	1	1	66	1	1	3.5/4
Cape Verde .....	4	70	7	66	8	7	44	8	7	3.5/4
Cayman Islands .....	7	70	9	44	8	9	44	8	9	3.5/4
Central African Republic .....	n/a	n/a	7	66	8	7	66	8	7	3.5/4
Chad .....	4	70	7	66	8	7	44	8	7	3.5/4
Chile .....	8	70	9	66	2	9	44	2	9	3.5/4
China .....	6	70	14	66	3	14	66	3	3	3.5/4
Colombia .....	8	70	9	44	2	9	66	2	9	3.5/4
Comoros .....	n/a	n/a	n/a	n/a	n/a	7	44	8	7	3.5/4
Congo, Democratic Republic of the .....	4	66	7	66	8	7	66	8	7	3.5/4
Congo, Republic of the .....	4	70	7	66	8	7	44	8	7	3.5/4
Costa Rica .....	8	70	9	66	8	9	66	8	9	3.5/4
Cote d'Ivoire (Ivory Coast) ..	4	70	7	66	8	7	66	8	7	3.5/4
Croatia .....	4	70	4	66	8	4	66	8	4	3.5/4
Cuba <sup>4</sup> .....	n/a	n/a	n/a	n/a	n/a	n/a	4	8	9	3.5/4
Curacao .....	7	70	9	66	8	9	44	8	9	3.5/4
Cyprus .....	6	70	4	70	8	4	70	8	4	3.5/4
Czech Republic .....	4	70	4	70	8	4	70	8	4	3.5/4
Denmark .....	5	70	5	66	4	5	66	4	5	3.5/4
Djibouti .....	4	70	7	44	8	7	44	8	7	3.5/4
Dominica .....	7	70	9	44	8	9	44	8	9	3.5/4
Dominican Republic .....	7	70	9	66	2	9	44	2	9	3.5/4
Ecuador .....	8	70	9	66	2	9	66	2	9	3.5/4
Egypt .....	6	70	8	44	7	8	66	7	8	3.5/4
El Salvador .....	8	70	9	66	8	9	44	8	9	3.5/4
Equatorial Guinea .....	n/a	n/a	7	44	8	7	22	8	7	3.5/4
Eritrea .....	4	70	7	66	8	7	44	8	7	3.5/4
Estonia .....	4	70	4	66	8	4	70	8	4	3.5/4
Ethiopia .....	4	70	8	66	8	8	66	8	8	3.5/4
Falkland Islands <sup>4</sup> .....	n/a	n/a	n/a	n/a	n/a	n/a	4	8	9	3.5/4
Faroe Islands .....	5	70	5	44	8	5	70	8	5	3.5/4
Fiji .....	8	70	6	66	8	6	44	8	6	3.5/4
Finland .....	5	70	5	66	4	5	70	4	5	3.5/4
France .....	3	70	13	66	4	13	66	4	5	3.5/4
French Guiana ..	8	70	9	66	8	9	66	8	9	3.5/4
French Polynesia ..	4	70	6	66	8	6	66	8	6	3.5/4
Gabon .....	4	70	7	66	8	7	44	8	7	3.5/4
Gambia .....	4	70	n/a	n/a	n/a	7	66	8	7	3.5/4
Georgia, Republic of .....	4	70	4	66	8	4	44	8	4	3.5/4
Germany .....	3	70	16	66	4	16	70	4	5	3.5/4
Ghana .....	4	70	7	66	8	7	66	8	7	3.5/4
Gibraltar .....	4	70	n/a	n/a	n/a	5	44	8	5	3.5/4
Great Britain and Northern Ireland .....	3	70	11	66	4	11	66	4	5	3.5/4
Greece .....	5	70	5	66	8	5	44	8	5	3.5/4
Greenland .....	5	70	n/a	n/a	n/a	5	66	8	5	3.5/4
Grenada .....	7	70	9	66	8	9	44	8	9	3.5/4
Guadeloupe .....	7	70	9	66	8	9	66	8	9	3.5/4
Guatemala .....	8	70	9	66	2	9	44	2	9	3.5/4
Guinea .....	4	70	7	44	8	7	66	8	7	3.5/4
Guinea-Bissau ..	n/a	n/a	7	44	8	7	66	8	7	3.5/4
Guyana .....	8	70	9	66	2	9	44	2	9	3.5/4
Haiti .....	7	70	9	66	8	9	55	8	9	3.5/4
Honduras .....	8	70	9	44	8	9	44	8	9	3.5/4
Hong Kong .....	3	70	3	66	3	3	66	3	3	3.5/4
Hungary .....	4	70	4	66	8	4	44	8	4	3.5/4
Iceland .....	5	70	5	66	8	5	70	8	5	3.5/4
India .....	6	70	6	70	5	6	44	5	6	3.5/4
Indonesia .....	6	70	6	66	3	6	44	3	6	3.5/4
Iran .....	n/a	n/a	n/a	n/a	n/a	8	44	8	8	3.5/4
Iraq .....	6	70	8	44	7	8	44	7	8	3.5/4
Ireland .....	3	70	5	66	4	5	66	4	5	3.5/4

Country	Global Express Guaranteed		Priority Mail Express International			Priority Mail International			First-Class Mail International and First-Class Package International Service	
	Price group	Max. wt. (lbs.)	Price group	Max. wt. (lbs.)	PMEI Flat Rate Envelopes price group <sup>1</sup>	Price group	Max. wt. (ozs./lbs.)	PMI Flat Rate Envelopes and Boxes price group <sup>2</sup>	Price group	Max. wt. (ozs./lbs.) <sup>3</sup>
Israel .....	6	70	8	44	7	8	44	7	5	3.5/4
Italy .....	3	70	5	66	4	5	66	4	5	3.5/4
Jamaica .....	7	70	9	66	8	9	22	8	9	3.5/4
Japan .....	3	70	12	66	3	12	66	3	3	3.5/4
Jordan .....	6	70	8	66	7	8	66	7	8	3.5/4
Kazakhstan .....	4	70	6	66	8	6	44	8	6	3.5/4
Kenya .....	4	70	7	70	8	7	70	8	7	3.5/4
Kiribati .....	n/a	n/a	6	66	8	6	44	8	6	3.5/4
Korea, Democratic People's Republic of (North Korea) <sup>5</sup>	n/a	n/a	n/a	n/a	n/a	n/a	4	8	6	3.5/4
Korea, Republic of (South Korea) .....	6	70	3	66	3	3	44	3	3	3.5/4
Kosovo, Republic of .....	4	70	n/a	n/a	n/a	5	70	8	5	3.5/4
Kuwait .....	6	70	8	66	8	8	66	8	8	3.5/4
Kyrgyzstan .....	4	70	6	66	8	6	44	8	6	3.5/4
Laos .....	8	70	6	66	8	6	44	8	6	3.5/4
Latvia .....	4	70	4	66	8	4	70	8	4	3.5/4
Lebanon .....	6	70	8	66	8	8	66	8	8	3.5/4
Lesotho .....	4	70	7	66	8	7	44	8	7	3.5/4
Liberia .....	4	70	7	44	8	7	44	8	7	3.5/4
Libya .....	4	70	n/a	n/a	n/a	8	44	8	8	3.5/4
Liechtenstein .....	5	70	5	66	8	5	66	8	5	3.5/4
Lithuania .....	4	70	4	70	8	4	70	8	4	3.5/4
Luxembourg .....	3	70	5	66	4	5	66	4	5	3.5/4
Macao .....	3	70	6	44	8	6	70	8	6	3.5/4
Macedonia (Republic of) .....	4	70	4	66	8	4	70	8	4	3.5/4
Madagascar .....	4	70	7	66	8	7	44	8	7	3.5/4
Malawi .....	4	70	7	44	8	7	66	8	7	3.5/4
Malaysia .....	6	70	6	66	8	6	66	8	6	3.5/4
Maldives .....	6	70	6	66	8	6	66	8	6	3.5/4
Mali .....	4	70	7	66	8	7	66	8	7	3.5/4
Malta .....	5	70	5	44	8	5	66	8	5	3.5/4
Martinique .....	7	70	9	66	8	9	66	8	9	3.5/4
Mauritania .....	4	70	7	66	8	7	44	8	7	3.5/4
Mauritius .....	4	70	7	66	8	7	44	8	7	3.5/4
Mexico .....	2	70	2	70	2	2	70	2	2	3.5/4
Moldova .....	4	70	4	70	8	4	70	8	4	3.5/4
Mongolia .....	4	70	6	66	3	6	66	3	6	3.5/4
Montenegro .....	4	70	n/a	n/a	n/a	5	70	8	5	3.5/4
Montserrat .....	7	70	n/a	n/a	n/a	9	44	8	9	3.5/4
Morocco .....	4	70	8	68	8	8	66	8	8	3.5/4
Mozambique .....	4	70	7	66	8	7	66	8	7	3.5/4
Namibia .....	4	70	7	22	8	7	44	8	7	3.5/4
Nauru .....	n/a	n/a	6	44	8	6	44	8	6	3.5/4
Nepal .....	6	70	6	69	8	6	44	8	6	3.5/4
Netherlands .....	3	70	17	66	4	17	66	4	5	3.5/4
New Caledonia .....	8	70	6	66	8	6	66	8	6	3.5/4
New Zealand .....	6	70	10	66	6	10	66	6	6	3.5/4
Nicaragua .....	8	70	9	55	8	9	66	8	9	3.5/4
Niger .....	4	70	7	70	8	7	70	8	7	3.5/4
Nigeria .....	4	70	7	66	8	7	66	8	7	3.5/4
Norway .....	5	70	5	66	4	5	66	4	5	3.5/4
Oman .....	6	70	8	66	8	8	44	8	8	3.5/4
Pakistan .....	6	70	6	66	8	6	70	8	6	3.5/4
Panama .....	8	70	9	66	8	9	70	8	9	3.5/4
Papua New Guinea .....	8	70	6	55	8	6	44	8	6	3.5/4
Paraguay .....	8	70	9	55	2	9	66	2	9	3.5/4
Peru .....	8	70	9	70	2	9	70	2	9	3.5/4
Philippines .....	6	70	6	44	3	6	44	3	6	3.5/4
Pitcairn Island .....	n/a	n/a	n/a	n/a	n/a	6	22	8	6	3.5/4
Poland .....	4	70	4	44	8	4	44	8	4	3.5/4
Portugal .....	5	70	5	66	4	5	66	4	5	3.5/4
Qatar .....	6	70	8	66	8	8	70	8	8	3.5/4
Reunion .....	4	70	n/a	n/a	n/a	9	66	8	9	3.5/4
Romania .....	4	70	4	70	8	4	70	8	4	3.5/4
Russia .....	4	70	4	70	8	4	44	8	4	3.5/4
Rwanda .....	4	70	7	66	8	7	66	8	7	3.5/4
Saint Helena .....	n/a	n/a	n/a	n/a	n/a	7	44	8	7	3.5/4
Saint Kitts and Nevis .....	7	70	9	66	8	9	44	8	9	3.5/4

Country	Global Express Guaranteed		Priority Mail Express International			Priority Mail International			First-Class Mail International and First-Class Package International Service	
	Price group	Max. wt. (lbs.)	Price group	Max. wt. (lbs.)	PMEI Flat Rate Envelopes price group <sup>1</sup>	Price group	Max. wt. (ozs./lbs.)	PMEI Flat Rate Envelopes and Boxes price group <sup>2</sup>	Price group	Max. wt. (ozs./lbs.) <sup>3</sup>
Saint Lucia .....	7	70	9	44	8	9	44	8	9	3.5/4
Saint Pierre and Miquelon .....	n/a	n/a	n/a	n/a	n/a	4	66	8	4	3.5/4
Saint Vincent and the Grenadines .....	7	70	9	44	8	9	22	8	9	3.5/4
Samoa .....	n/a	n/a	6	44	8	6	44	8	6	3.5/4
San Marino .....	3	70	5	66	8	5	66	8	5	3.5/4
Sao Tome and Principe .....	n/a	n/a	7	66	8	7	44	8	7	3.5/4
Saudi Arabia .....	4	70	8	66	7	8	66	7	8	3.5/4
Senegal .....	4	70	7	66	8	7	66	8	7	3.5/4
Serbia, Republic of .....	4	70	5	66	8	5	70	8	5	3.5/4
Seychelles .....	4	70	7	66	8	7	70	8	7	3.5/4
Sierra Leone .....	n/a	n/a	7	66	8	7	66	8	7	3.5/4
Singapore .....	3	70	6	66	3	6	66	3	6	3.5/4
Sint Maarten .....	7	70	9	66	8	9	44	8	9	3.5/4
Slovak Republic (Slovakia) .....	4	70	5	66	4	5	66	4	5	3.5/4
Slovenia .....	4	70	5	66	4	5	66	4	5	3.5/4
Solomon Islands .....	n/a	n/a	6	66	8	6	44	8	6	3.5/4
Somalia .....	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
South Africa .....	4	70	7	66	8	7	66	8	7	3.5/4
Spain .....	5	70	5	66	4	5	44	4	5	3.5/4
Sri Lanka .....	6	70	6	66	8	6	66	8	6	3.5/4
Sudan .....	n/a	n/a	7	66	8	7	44	8	7	3.5/4
Suriname .....	8	70	n/a	n/a	n/a	9	44	8	9	3.5/4
Swaziland .....	4	70	7	66	8	7	44	8	7	3.5/4
Sweden .....	5	70	5	66	4	5	66	4	5	3.5/4
Switzerland .....	5	70	5	66	4	5	66	4	5	3.5/4
Syrian Arab Republic (Syria) ..	n/a	n/a	8	44	8	8	70	8	8	3.5/4
Taiwan .....	3	70	6	33	8	6	44	8	6	3.5/4
Tajikistan .....	n/a	n/a	6	66	8	6	66	8	6	3.5/4
Tanzania .....	4	70	7	66	8	7	66	8	7	3.5/4
Thailand .....	6	70	6	66	3	6	66	3	6	3.5/4
Timor-Leste, Democratic Republic of .....	6	70	n/a	n/a	n/a	6	44	8	6	3.5/4
Togo .....	4	70	7	66	8	7	70	8	7	3.5/4
Tonga .....	4	70	6	66	8	6	44	8	6	3.5/4
Trinidad and Tobago .....	7	70	9	66	8	9	44	8	9	3.5/4
Tristan da Cunha .....	n/a	n/a	n/a	n/a	n/a	7	22	8	7	3.5/4
Tunisia .....	4	70	8	66	8	8	66	8	8	3.5/4
Turkey .....	6	70	4	66	7	4	66	7	4	3.5/4
Turkmenistan .....	n/a	n/a	6	66	8	6	44	8	6	3.5/4
Turks and Caicos Islands .....	7	70	9	66	8	9	44	8	9	3.5/4
Tuvalu .....	n/a	n/a	n/a	n/a	n/a	6	55	8	6	3.5/4
Uganda .....	4	70	7	66	8	7	66	8	7	3.5/4
Ukraine .....	4	70	4	44	8	4	66	8	4	3.5/4
United Arab Emirates .....	6	70	8	70	7	8	70	7	8	3.5/4
Uruguay .....	8	70	9	44	2	9	66	2	9	3.5/4
Uzbekistan .....	4	70	6	66	8	6	70	8	6	3.5/4
Vanuatu .....	8	70	6	55	8	6	44	8	6	3.5/4
Vatican City .....	3	70	5	66	8	5	44	8	5	3.5/4
Venezuela .....	8	70	9	66	2	9	66	2	9	3.5/4
Vietnam .....	6	70	6	66	3	6	70	3	6	3.5/4
Wallis and Futuna Islands ..	4	70	n/a	n/a	n/a	6	66	8	6	3.5/4
Yemen .....	6	70	8	66	7	8	66	7	8	3.5/4
Zambia .....	4	70	7	66	8	7	66	8	7	3.5/4
Zimbabwe .....	4	70	7	44	8	7	44	8	7	3.5/4

\* \* \* \* \*

**Individual Country Listings**  
**Country Conditions for Mailing**

\* \* \* \* \*

**Priority Mail Express International (220)**

\* \* \* \* \*

[For every country listing that contains Priority Mail Express

International—Flat Rate Envelopes and Flat Rate Boxes, remove Flat Rate Boxes from the heading and the text, to read as follows:]

**Priority Mail Express International—Flat Rate Envelopes**

Flat Rate Envelopes: The maximum weight is 4 pounds. Refer to Notice 123, *Price List*, for the applicable retail, Commercial Base, or Commercial Plus price.

\* \* \* \* \*

**Priority Mail International (230)**

[For every country listing that includes a Note about ordinary Priority Mail International including indemnity at no cost, remove the note.]

\* \* \* \* \*

We will publish an appropriate amendment to 39 CFR part 20 to reflect these changes.

**Stanley F. Mires,**

*Attorney, Federal Compliance.*

[FR Doc. 2015-26918 Filed 10-23-15; 8:45 am]

BILLING CODE 7710-12-P

**POSTAL SERVICE****39 CFR Part 111****Domestic Competitive Products Pricing and Mailing Standards Changes**

**AGENCY:** Postal Service™.

**ACTION:** Final rule.

**SUMMARY:** The Postal Service is amending *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM®), to reflect changes to prices and mailing standards for competitive products.

**DATES:** *Effective Date:* January 17, 2016.

**FOR FURTHER INFORMATION CONTACT:**

Karen Key at (202) 268-7492 or Garry Rodriguez at (202) 268-7281.

**SUPPLEMENTARY INFORMATION:** This final rule describes new prices and product features for competitive products, by class of mail, established by the Governors of the United States Postal Service. New prices are available under Docket Number CP2016-9 on the Postal Regulatory Commission's (PRC) Web site at <http://www.prc.gov>, and also located on the Postal Explorer® Web site at <http://pe.usps.com>.

The Postal Service will revise the *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM), to reflect changes to prices and mailing standards for the following competitive products:

- Priority Mail Express®.
- Priority Mail®.
- First-Class Package Service®.
- Parcel Select®.
- Standard Post™.
- Extra Services.

- Return Services.
- Mailer Services.
- Recipient Services.

Competitive product prices and changes are identified by product as follows:

**Priority Mail Express***Prices*

Overall, Priority Mail Express prices will increase 15.6 percent. Priority Mail Express will continue to offer zoned Retail, Commercial Base™, and Commercial Plus™ pricing tiers.

Retail prices will increase an average of 14.4 percent. The price for the Retail Flat Rate Envelope, Legal Flat Rate Envelope, and Padded Flat Rate Envelope will increase to \$22.95.

Commercial Base prices offer lower prices to customers who use authorized postage payment methods. Commercial Base prices will increase an average of 17.7 percent. Commercial Base pricing offers an average 10.0 percent discount off retail prices.

The Commercial Plus price category offers price incentives to large volume customers. Commercial Plus prices will increase an average of 48.2 percent. The Postal Service is proposing this increase to match Commercial Plus prices with Commercial Base prices as part of a pricing strategy with the long-term goal of eliminating the Commercial Plus price category to reflect the industry standard of publishing only one set of commercial price tables. Commercial Plus customers may be transitioned to Negotiated Service Agreements (NSAs) for additional discounts.

*Priority Mail Express Flat Rate Box*

The Postal Service will discontinue the use of Priority Mail Express Flat Rate Boxes as a product offering. As of January 17, 2016, Priority Mail Express Flat Boxes will be charged the applicable Priority Mail Express price based on weight and zone.

**Priority Mail***Prices*

Overall, Priority Mail prices will increase 9.8 percent. Priority Mail will continue to offer zoned Retail, Commercial Base, and Commercial Plus pricing tiers.

Retail prices will increase an average of 8.6 percent. The Flat Rate Envelope price will increase to \$6.45, the Legal Flat Rate Envelope will also increase to \$6.45, and the Padded Flat Rate Envelope will increase to \$6.80. The Small Flat Rate Box price will increase to \$6.80 and the Medium Flat Rate Boxes will increase to \$13.45. The Large Flat Rate Box will increase to \$18.75

and the Large APO/FPO/DPO Flat Rate Box will increase to \$16.75.

Commercial Base prices offer lower prices to customers who use authorized postage payment methods. Commercial Base prices will increase an average of 9.4 percent. Commercial Base pricing offers an average 13.9 percent discount off retail prices.

The Commercial Plus price category offers price incentives to large volume customers. Commercial Plus prices will increase an average of 13.3 percent. The Postal Service is proposing this increase to bring Commercial Plus prices within three percent of Commercial Base prices as part of a pricing strategy with the long-term goal of eliminating the Commercial Plus price category to reflect the industry standard of publishing only one set of commercial price tables. Commercial Plus customers may be transitioned to Negotiated Service Agreements (NSAs) for additional discounts.

*Critical Mail*

The Postal Service will discontinue the Critical Mail (Critical Mail and Critical Mail with Signature) product offering. As of January 17, 2016, Critical Mail letters and flats will be charged the Commercial Plus Flat Rate Envelope price. Critical Mail with signature letters and flats will be charged the Commercial Plus Flat Rate Envelope price and Signature Confirmation™ customer generated electronic label fee.

*Priority Mail Regional Rate Boxes*

The Postal Service will implement a two-tier zone surcharge for Regional Rate Boxes A and B paid at retail. Zones 1-4 will have a \$2.25 surcharge and Zones 5-9 will have a \$1.00 surcharge.

Additionally, the Postal Service will discontinue the Priority Mail Regional Rate Box® C to simplify this product offering. As of January 17, 2016, a Regional Rate Box C will be charged the applicable Priority Mail price based on weight and zone.

**First-Class Package Service***Prices*

Overall, First-Class Package Service prices will increase 12.8 percent. The Intelligent Mail® package barcode (IMpb) will continue to provide free USPS tracking and confirmation of delivery with these parcels.

*First-Class Package Service Restructuring*

The Postal Service will discontinue First-Class Package Service Commercial Plus pricing and restructure First-Class Package Service commercial parcel prices to simplify this product offering.

First-Class Package Service commercial parcels will only be a single-piece product with prices starting at 1 ounce up to less than 16 ounces. First-Class Package Service commercial parcels will not be sealed against inspection.

**Parcel Select**

*Prices*

Parcel Select Destination Entry prices will increase an average of 4.9 percent and Parcel Select Ground (formerly Parcel Select Nonpresort) prices will increase an average of 1.9 percent. The prices for Parcel Select Lightweight® (PSLW) will increase an average of 23.5 percent.

The IMpb will continue to provide free USPS tracking and confirmation of delivery with all Parcel Select parcels.

*Parcel Select Nonpresort*

The Postal Service will rename Parcel Select Nonpresort as Parcel Select Ground. No changes to the product features or mailing standards are being made as a result of this change.

*Parcel Select ONDC and NDC*

The Postal Service will discontinue the Parcel Select ONDC and NDC price categories to simplify product offerings. As of January 17, 2016, parcels entered at Parcel Select ONDC and NDC prices will be charged the applicable Parcel Select Ground prices.

*Parcel Select Lightweight*

The Postal Service will consolidate the Parcel Select Lightweight Machinable and Irregular price tables to simplify this product offering. The new price table, similar to the existing Irregular price table, will be titled “Parcel Select Lightweight-Commercial Parcels” and will have 5-Digit, SCF, NDC, and Mixed NDC/Single Piece price levels. The weight increments will start at 1 ounce and include pieces up to less than 16 ounces. Mail preparation will remain the same for machinable and irregular presorted parcels, and will be subject to the applicable price levels based on sortation.

**Standard Post**

Overall, Standard Post prices will increase an average of 10.0 percent.

*Standard Post*

The Postal Service will rename Standard Post as Retail Ground. No changes to the product features or mailing standards are being made as a result of this change.

**Extra Services**

*Adult Signature Service*

Adult Signature Required and Adult Signature Restricted Delivery service prices are increasing 3.6 and 3.5 percent respectively. The price for Adult Signature Required will increase to \$5.70 and Adult Signature Restricted Delivery will increase to \$5.95.

**Return Services**

*Parcel Return Service*

Overall, Parcel Return Service (PRS) prices will increase an average of 5.0 percent.

Return Sectional Center Facility (RSCF) prices will increase an average of 5.0 percent and Return Delivery Unit (RDU) prices will increase an average of 5.0 percent.

The Parcel Return Service annual permit fee and annual account maintenance fee will not change at this time.

*Parcel Return Service Return Network Distribution Center (RNDC)*

The Postal Service will discontinue the RNDC price option to simplify this product offering. As of January 17, 2016, parcels entered at RNDC prices will be charged the applicable Parcel Select Ground price.

**Mailer Services**

*Treatment of Mail—Treatment of Undeliverable Parcel Select*

The Postal Service is introducing a reduced Additional Service Fee for Parcel Select shippers who use IMpb™ ACST™ with Shipper Paid Forward/Return, when those packages are forwarded or returned. The Postal Service will charge the ACS & Shipper Paid Forward/Return Additional Service Fee of \$1.50 to Parcel Select shippers when their UAA parcels have been processed using IMpb ACS with Shipper Paid Forward/Return. With certain ACS Shipper Paid ancillary services, the forwarding or return postage and ACS & Shipper Paid Forward/Return additional service fee for UAA Parcel Select may be invoiced through the ACS billing process.

*Premium Forwarding Service*

Premium Forwarding Service® (PFS®) prices will increase an average of 3.6 percent. The enrollment fee paid at the retail counter will increase to \$18.65 and the residential and commercial enrollment fee paid online will increase to \$17.10 per application. The price of the weekly reshipment charge will increase to \$18.65.

*USPS Package Intercept*

The USPS Package Intercept™ fee will increase 3.3 percent to \$12.55.

*Pickup on Demand Service*

The Pickup on Demand® service daily fee will remain at \$20.00 for January 17, 2016.

**Recipient Services**

*Post Office Box Service*

The competitive Post Office Box™ service prices will increase an average of 3.5 percent within the modified price ranges.

**Other**

*Click-N-Ship*

The Postal Service is restructuring Click-N-Ship® to offer only retail prices. Click-N-Ship will no longer be an authorized payment method for Priority Mail Express and Priority Mail Commercial Base pricing.

**Resources**

The Postal Service provides additional resources to assist customers with this price change for competitive products. These tools include price lists, downloadable price files, and **Federal Register** Notices, which may be found on the Postal Explorer® Web site at [pe.usps.com](http://pe.usps.com).

**List of Subjects in 39 CFR Part 111**

Administrative practice and procedure, Postal Service.

The Postal Service adopts the following changes to *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM), incorporated by reference in the *Code of Federal Regulations*. See 39 CFR 111.1.

Accordingly, 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 *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)**

\* \* \* \* \*

**100 Retail Mail**

\* \* \* \* \*

**110 Priority Mail Express**

**113 Prices and Eligibility**

**1.0 Priority Mail Express Prices and Fees**

\* \* \* \* \*

**1.3 Flat Rate Packaging**

*[Revise the first sentence of 1.3 to read as follows:]*

Only USPS-produced or approved Flat Rate Envelopes are eligible for the Flat Rate price and are charged a flat rate, regardless of the actual weight (up to 70 pounds) of the mailpiece or domestic destination. \* \* \*

\* \* \* \* \*

**114 Postage Payment Methods**

*[Revise the heading of 1.0 to read as follows:]*

**1.0 Basic Standards for Postage Payment**

**1.1 Payment Method**

*[Revise the first sentence of 1.1 to read as follows:]*

Retail Priority Mail Express postage may be paid with adhesive stamps (see 604.1.0), with meter stamps (see 604.4.0) affixed to each piece, or with Click-N-Ship. \* \* \*

\* \* \* \* \*

**115 Mail Preparation**

**1.0 Priority Mail Express Supplies**

\* \* \* \* \*

**1.2 Sealing Flat Rate Packaging**

*[Revise the text of 1.2 to read as follows:]*

When sealing a Flat Rate Envelope, the container flap must be able to close within the normal fold. Tape may be applied to the flap and seams to reinforce the container provided the design of the container is not enlarged by opening the sides, and the container is not reconstructed in any way.

\* \* \* \* \*

**120 Priority Mail**

**123 Prices and Eligibility**

**1.0 Priority Mail Prices and Fees**

\* \* \* \* \*

**1.6 Regional Rate Boxes**

*[Delete the heading 1.6.1 and move the text under 1.6. Revise the text of 1.6 to read as follows:]*

Regional Rate Box prices are available to Priority Mail Commercial Base or Commercial Plus customers who use USPS-produced Priority Mail Regional Rate Boxes under 223.1.8. Regional Rate Boxes paid at retail are charged a fee based on zone (1–4 or 5–9), in addition

to the applicable Commercial Base or Commercial Plus postage. Regional Rate Boxes that exceed the maximum weight as specified in 223.1.8 or have container flaps that do not close within the normal folds are not eligible for Regional Rate Box prices and are assessed the applicable single-piece Priority Mail price.

*[Delete current 1.6.2 in its entirety.]*

\* \* \* \* \*

**124 Postage Payment Methods**

**1.0 Basic Standards for Postage Payment**

**1.1 Payment Methods**

*[Revise the text of 1.1 to read as follows:]*

Priority Mail postage may be paid with postage stamps (see 604.1.0), with meter stamps (see 604.4.0) affixed to each piece, or with Click-N-Ship.

\* \* \* \* \*

*[Revise section 150 and the DMM globally to change the name from “Standard Post” to “Retail Ground”.]*

**150 Retail Mail Retail Ground**

\* \* \* \* \*

**200 Commercial Mail Letters, Cards, Flats, and Parcels**

**201 Physical Standards**

\* \* \* \* \*

**2.0 Physical Standards for Nonmachinable Letters**

\* \* \* \* \*

*[Revise the heading of 2.5 to read as follows:]*

**2.5 Priority Mail Express and Priority Mail Letters**

*[Delete the second sentence of 2.5]*

\* \* \* \* \*

**3.0 Physical Standards for Machinable and Automation Letters and Cards**

\* \* \* \* \*

**3.5 Maximum Weight, Machinable and Automation Letters and Cards**

The following maximum weight limits apply:

*[Delete item a and renumber items b through d as items a through c.]*

\* \* \* \* \*

**4.0 Physical Standards for Flats**

\* \* \* \* \*

**4.7 Flat-Size Pieces Not Eligible for Flat-Size Prices**

\* \* \* \* \*

**Exhibit 4.7b Pricing for Flats Exceeding Maximum Deflection**

\* \* \* \* \*

*[Revise the text in Exhibit 4.7b under “Eligibility with failed deflection” column to read as follows:]*

**First-Class Mail Presorted (Nonautomation)**

Eligibility as presented	Eligibility with failed deflection
Presorted Flat	Single-piece flat or First-Class Package Service.

\* \* \* \* \*

**5.0 Physical Standards for Nonautomation Flats**

\* \* \* \* \*

*[Revise the heading of 5.5 to read as follows:]*

**5.5 Priority Mail Express and Priority Mail Flats**

*[Delete the second sentence of 5.5.]*

**6.0 Physical Standards for Automation Flats**

\* \* \* \* \*

**6.2 Additional Criteria for Automation Flats**

\* \* \* \* \*

**6.2.2 Maximum Weight**

Maximum weight limits are as follows:

*[Delete item a and renumber items b through e as items a through d.]*

\* \* \* \* \*

**8.0 Physical Standards by Class of Mail**

\* \* \* \* \*

**8.3 First-Class Package Service Parcels**

**8.3.1 Weight**

*[Revise the text of 8.3.1 to read as follows:]*

First-Class Package Service parcels must weigh less than 16 ounces.

\* \* \* \* \*

**202 Elements on the Face of a Mailpiece**

\* \* \* \* \*

**3.0 Placement and Content of Mail Markings**

\* \* \* \* \*

*[Revise the heading of 3.3 to read as follows:]*

**3.3 Priority Mail Express and Priority Mail Markings**

\* \* \* \* \*

**3.6 First-Class Package Service Markings**

[Revise the text of 3.6 in its entirety to read as follows:]

The basic required marking “First-Class Package” or “First-Class PKG” must be printed as part of, directly below, or to the left of the postage on all parcels.

\* \* \* \* \*

**3.7 Parcel Select, Bound Printed Matter, Media Mail, and Library Mail Markings**

**3.7.1 Basic Markings**

\* \* \* Optionally, the basic required marking may be printed on the shipping address label as service indicators composed of a service icon and service banner (see Exhibit 3.7.1):

\* \* \* \* \*

[Revise the second sentence of item b to read as follows:]

b. \* \* \* The appropriate marking (e.g., “PARCEL SELECT”, “MEDIA MAIL”) must be preceded by the text “USPS” and be printed in minimum 20-point bold sans serif typeface, uppercase letters, centered within the banner, and bordered above and below by minimum 1-point separator lines. \* \* \*

\* \* \* \* \*

**3.7.2 Parcel Select Markings**

\* \* \* The following product markings are required:

\* \* \* \* \*

[Delete items b and c, and renumber items d and e as items b and c.]

[Revise renumbered item b to read as follows:]

b. Ground—“Parcel Select Ground” or “Parcel Select GND”.

\* \* \* \* \*

**210 Priority Mail Express**

**213 Prices and Eligibility**

**1.0 Prices and Fees**

\* \* \* \* \*

**1.3 Commercial Base Prices**

Priority Mail Express Commercial Base prices are less than Priority Mail Express retail prices (see Notice 123—Price List). These prices are available to:

\* \* \* \* \*

[Delete item b and renumber items c through e as items b through d.]

\* \* \* \* \*

**1.5 Flat Rate Packaging**

[Revise the first sentence of 1.4 to read as follows:]

Only USPS-produced or approved Flat Rate Envelopes are eligible for the Flat Rate price and are charged a flat

rate, regardless of the actual weight (up to 70 pounds) of the mailpiece or domestic destination. \* \* \*

\* \* \* \* \*

**214 Postage Payment and Documentation**

**1.0 Basic Standards for Postage Payment Options**

\* \* \* \* \*

**1.1 Commercial Base Pricing**

Commercial Base Priority Mail Express postage may be paid with:

\* \* \* \* \*

[Delete item b and renumber items c through e as items b through d.]

\* \* \* \* \*

**215 Mail Preparation**

**1.0 General Information for Mail Preparation**

\* \* \* \* \*

**1.2 Sealing Flat Rate Packaging**

[Revise the text of 1.2 to read as follows:]

When sealing a Flat Rate Envelope, the container flap must be able to close within the normal fold. Tape may be applied to the flap and seams to reinforce the container provided the design of the container is not enlarged by opening the sides and the container is not reconstructed in any way.

\* \* \* \* \*

**2.0 Priority Mail Express 1-Day and 2-Day**

**2.1 Mailing Label**

[Revise the first sentence of 2.1 to read as follows:]

For each Priority Mail Express item, the mailer must complete Label 11–B or Label 11–F, Label 11–HFPU for Hold For Pickup service, or a single-ply Priority Mail Express label generated through a USPS-approved method.

\* \* \* \* \*

\* \* \* \* \*

**220 Priority Mail**

**223 Prices and Eligibility**

**1.0 Prices and Fees**

\* \* \* \* \*

**1.2 Commercial Base Prices**

For prices, see Notice 123—Price List. The Commercial Base prices are available for:

[Delete item a and renumber items b through f as items a through e.]

\* \* \* \* \*

[Delete 1.4, Critical Mail Prices, in its entirety and renumber items 1.5 through 1.13 as items 1.4 through 1.12.]

\* \* \* \* \*

**1.8 Regional Rate Box Prices**

\* \* \* Regional Rate Box options are:

\* \* \* \* \*

[Delete item c.]

\* \* \* \* \*

**1.9 Hold For Pickup**

[Revise the text of renumbered 1.9 to read as follows:]

Priority Mail is eligible for Hold For Pickup service under 508.7.0.

\* \* \* \* \*

**1.11 Determining Single-Piece Weight**

[Revise the text of renumbered 1.11 to read as follows:]

To determine single-piece weight in any mailing of nonidentical-weight pieces, weigh each piece individually. To determine single-piece weight in a mailing of identical-weight pieces, weigh a sample group of at least 10 randomly selected pieces and divide the total sample weight by the number of pieces in the sample. Except for mailers using eVS, express all single-piece weights in decimal pounds rounded off to two decimal places. Mailers using eVS may round off to four decimals, and eVS will automatically round to the appropriate decimal place. If a customer is using a manifest mailing system, the manifest weight field must be properly completed by adhering to the rules relative to the specific manifest.

\* \* \* \* \*

**3.0 Basic Eligibility Standards for Priority Mail**

**3.1 Definition**

[Revise the second sentence of 3.1 to read as follows:]

\* \* \* Lower weight limits apply to Commercial Plus cubic (see 1.5); Regional Rate Boxes (see 1.9); APO/FPO mail subject to 703.2.0 and 703.4.0 and Department of State mail subject to 703.3.0.

[Delete 3.2 in its entirety and renumber 3.3 through 3.5 as 3.2 through 3.4.]

**3.2 IMpb Standards**

[Revise the first sentence of renumbered 3.2 to read as follows:]

Unless authorized to use a unique IMb on Priority Mail letters and flats prepared in high-speed environments, all Priority Mail pieces must bear an Intelligent Mail package barcode prepared under 708.5.0. \* \* \*

\* \* \* \* \*

**3.4 Matter Closed Against Postal Inspection**

*[Revise the text of renumbered 3.4 to read as follows:]*

Priority Mail matter is closed against postal inspection.

\* \* \* \* \*

**224 Postage Payment and Documentation****1.0 Basic Standards for Postage Payment****1.1 Postage Payment Options****1.1.1 Commercial Base Pricing**

Priority Mail Commercial Base and Regional Rate Box postage may be paid with:

*[Delete item a and renumber items b through e as items a through d.]*

\* \* \* \* \*

*[Delete 1.1.3, Critical Mail Pricing, in its entirety and renumber 1.1.4 as 1.1.3.]*

\* \* \* \* \*

**225 Mail Preparation****1.0 General Information for Mail Preparation****1.1 Priority Mail Packaging Provided by the USPS**

*[Delete the last sentence in 1.1.]*

\* \* \* \* \*

*[Delete 4.0, Additional Standards for Preparing Critical Mail, in its entirety and renumber 5.0 as 4.0.]*

\* \* \* \* \*

**226 Enter and Deposit****1.0 Deposit****1.1 General**

*[Revise the first sentence of 1.1 to read as follows:]*

Mailpieces bearing postage evidencing indicia must be deposited in a collection box or at a postal facility within the ZIP Code shown in the indicia, except as permitted under 2.0 or 604.4.6.3. \* \* \*

\* \* \* \* \*

**250 Parcel Select**

*[Revise 250 and the DMM globally to change the name of "Parcel Select Nonpresort" to "Parcel Select Ground".]*

**253 Prices and Eligibility****1.0 Prices and Fees****1.1 Price Application**

\* \* \* The price categories for Parcel Select are as follows:

\* \* \* \* \*

*[Delete item b and renumber items c and d as b and c.]*

*[Revise renumber item b to read as follows:]*

b. Ground

\* \* \* \* \*

**1.2 Parcel Select Prices**

*[Revise the first sentence of 1.2 to read as follows:]*

Pricing is available for Parcel Select at the Destination Entry and Parcel Select Ground levels. \* \* \*

\* \* \* \* \*

**2.0 Content Standards****2.1 Definition of a Parcel**

*[Revise the second sentence of 2.1 to read as follows:]*

\* \* \* When postage is paid using USPS-approved PC Postage in conjunction with barcoded Parcel Select Ground mailings, there is no minimum volume.

\* \* \* \* \*

**4.0 Price Eligibility for Parcel Select and Parcel Select Lightweight**

\* \* \* \* \*

*[Delete 4.2 in its entirety and renumbered 4.3 through 4.8 as 4.2 through 4.7.]*

\* \* \* \* \*

**4.3 Parcel Select Lightweight**

\* \* \* \* \*

**4.3.2 Price Application**

*[Revise the first sentence of renumbered 4.3.2 to read as follows:]*

Prices for Parcel Select Lightweight apply to parcels that meet the eligibility standards in 2.0 and 4.4 and the preparation standards in 255.7.0, 705.6.0, or 705.8.0. \* \* \*

\* \* \* \* \*

*[Delete renumbered 4.6, Delivery and Return Addresses, in its entirety and renumber 4.7 as 4.6.]*

\* \* \* \* \*

**254 Postage Payment and Documentation****1.0 Basic Standards for Postage Payment****1.1 Postage Payment Options**

Mailing fees must be paid for the current 12-month period at the Postal Service facility where postage is paid for the mailing.

*[Revise item a to read as follows:]*

a. Permit imprint may be used for identical-weight pieces provided the mail can be separated at acceptance into groups that each contain pieces subject to the same combination of prices.

\* \* \* \* \*

**2.0 Mailing Documentation**

\* \* \* \* \*

**2.2 Other Documentation**

*[Revise the first sentence of 2.2 to read as follows:]*

When presented for acceptance, documentation of postage by entry office and presort level (e.g., by DNDC and by 5-digit ZIP Code for DSCF and DDU prices) is required under 705.2.0 through 705.4.0. \* \* \*

\* \* \* \* \*

**255 Mail Preparation****1.0 General Information for Mail Preparation**

\* \* \* \* \*

**1.8 Parcel Select Markings**

*[Revise the text of 1.8 to read as follows:]*

Each piece in a Parcel Select mailing must bear a price marking under 202.3.7.2. Markings must appear in either the postage area described in 202.3.7, or in the address area on the line directly above or two lines above the address if the marking appears alone (when no other information appears on that line). The "Retail Ground" marking is not allowed on any Parcel Select mailpiece.

\* \* \* \* \*

*[Delete 5.0, Preparing NDC Presort and ONDC Presort, in its entirety, and renumber 6.0 and 7.0 as 5.0 and 6.0.]*

\* \* \* \* \*

**6.0 Preparing Parcel Select Lightweight****6.1 Basic Standards**

*[Revise the introductory text of renumbered 6.1 to read as follows:]*

All mailings and all pieces in each mailing at Parcel Select Lightweight prices are subject to the specific preparation standards in 7.2 and 7.3, and to these general standards:

\* \* \* \* \*

**256 Enter and Deposit**

\* \* \* \* \*

**2.0 Deposit**

\* \* \* \* \*

**2.5 Mail Separation and Presentation of Destination Entry Mailings**

\* \* \* Mailers presenting destination entry mailings to the Postal Service must meet the following requirements:

*[Revise the first sentence of item a to read as follows:]*

a. Mark each DNDC, DSCF, or DDU Parcel Select piece as "Parcel Select," according to 202.3.7.2. \* \* \*

\* \* \* \* \*



**280 First-Class Package Service**

**283 Prices and Eligibility**

**1.0 Prices and Fees for First-Class Package Service**

\* \* \* \* \*

*[Revise the heading and text of 1.2 to read as follows:]*

**1.2 Price Determination for First-Class Package Service**

First-Class Package Service prices start at 1 ounce and must weigh less than 16 ounces. Any fraction of an ounce is considered a whole ounce.

**1.3 Commercial Prices**

*[Revise the introductory text of 1.3 to read as follows:]*

Commercial prices are available when paid by one of the following methods:

\* \* \* \* \*

*[Delete 1.4, Commercial Plus Prices, in its entirety and renumber 1.5 through 1.8 as 1.4 through 1.7.]*

**1.4 Surcharge**

A surcharge applies for parcels that are irregularly shaped, such as rolls, tubes, and triangles.

\* \* \* \* \*

*[Delete renumbered 1.5, Presort Mailing Fee, 1.6, Computing Postage for First-Class Package Service, and 1.7, Determining Single-Piece Weight in their entirety.]*

\* \* \* \* \*

**2.0 Content Standards for First-Class Package Service Parcels**

**2.1 General**

*[Revise the text of 2.1 to read as follows:]*

In addition to restricted material described in 601.8.0, parcels mailed at First-Class Package Service prices may not contain documents or personal correspondence, except that such parcels may contain invoices, receipts, incidental advertising, and other documents that relate in all substantial respects to merchandise contained in the parcels.

**2.2 Matter Required To Be Mailed as First-Class Mail**

*[Revise the introductory text of 2.2 to read as follows:]*

See 233.2.0 for a detailed description of matter required to be mailed as First-Class Mail or Priority Mail. The following types of contents must be mailed as First-Class Mail or -Priority Mail:

\* \* \* \* \*

*[Delete 2.3, Restricted Air Transportation, in its entirety.]*

*[Revise the heading of 3.0 to read as follows:]*

**3.0 Basic Eligibility Standards for First-Class Package Service**

\* \* \* \* \*

**3.2 Defining Characteristics**

**3.2.1 Inspection of the Contents**

*[Revise the text of 3.2.1 to read as follows:]*

Articles mailed at First-Class Package Service prices are not sealed against postal inspection. Regardless of physical closure, the mailing of articles at First-Class Package Service prices constitutes consent by the mailer to postal inspection of the contents.

\* \* \* \* \*

**3.3 Additional Basic Standards**

*[Revise the introductory text of 3.3 to read as follows:]*

All First-Class Package Service parcels must:

\* \* \* \* \*

*[Revise the text of item b to read as follows:]*

b. Bear a delivery address that includes the correct ZIP Code or ZIP+4.

*[Delete 3.5, Move Update Standard, and 3.6 ZIP Code Accuracy in their entirety.]*

\* \* \* \* \*

*[Revise the heading of 4.0 to read as follows:]*

**4.0 Price Eligibility for First-Class Package Service**

*[Delete 4.1 through 4.4 and move the text under 4.5 as new 4.0 to read as follows:]*

Single-piece prices apply to nonpresorted parcels mailed under 285.1.0.

**248 Postage Payment and Documentation**

\* \* \* \* \*

*[Revise the heading of 2.0 to read as follows:]*

**2.0 Postage Payment for First-Class Package Service**

**2.1 Permit Imprint Postage**

*[Revise the second sentence of 2.1 to read as follows:]*

\* \* \* All mail manifested using the Electronic Verification System (eVS) under 705.2.9 must be paid using a permit imprint. \* \* \*

*[Revise the heading and text of 2.2 to read as follows:]*

**2.2 Affixed Payment for First-Class Package Service**

Each First-Class Package Service parcel bearing postage evidencing

system indicia (IBI Meter or PC Postage) must bear the full numerical value of postage at the First-Class Package Service price for which it qualifies.

\* \* \* \* \*

**285 Mail Preparation**

*[Delete 1.0, 2.0, 3.0, and 4.0 in their entirety and add a new 1.0 to read as follows:]*

**1.0 Preparation for First-Class Package Service**

The following standards apply to single-piece First-Class Package Service:

a. Each piece is required to bear the markings under 202.3.6.

b. There are no sorting requirements for single-piece First-Class Package Service parcels.

\* \* \* \* \*

**286 Enter and Deposit**

**1.0 Deposit**

\* \* \* \* \*

**1.2 Approved Collections**

The USPS may collect First-Class Package Service parcels at a mailer's facility if part of an approved collection service for other classes of mail; space is available on the transportation; and:

\* \* \* \* \*

*[Revise the text of item c to read as follows:]*

c. Postage is paid with postage evidencing system postage.

*[Delete 1.3, Permit Imprint Collection, in its entirety.]*

**2.0 Verification**

*[Delete the heading 2.1 and move the text under 2.0. Revise the text of 2.0 to read as follows:]*

Mailings are subject to USPS procedures to verify correct postage payment. The return of mailings to the mailer's facility for reworking is the mailer's responsibility.

*[Delete current 2.2 Timeframe for Corrective Action, and 2.3, Payment at Single-Piece Price Rather than Correcting Errors, in their entirety.]*

**500 Additional Mailing Services**

\* \* \* \* \*

**503 Extra Services**

**1.0 Basic Standards for All Extra Services**

\* \* \* \* \*

**1.4 Matter Eligible for Extra Services**

**1.4.1 Eligible Matter**

\* \* \* \* \*

**Exhibit 1.4.1 Eligible Matter—  
Domestic Destinations**

*[Delete “Critical Mail” in the “Eligible Mail Class” column under the following Extra Services: Insurance, Signature Confirmation, and Adult Signature Required.]*

\* \* \* \* \*

**4.0 Insured Mail**

\* \* \* \* \*

**4.3 Basic Standards****4.3.1 Description**

Insured mail is subject to the basic standards in 1.0; see 1.4 for eligible matter. The following additional standards apply to insured mail:

\* \* \* \* \*

*[Revise item e to read as follows:]*

e. First-Class Mail, First-Class Package Service, and Priority Mail may be insured, if it contains matter that is eligible to be mailed at Standard Mail, Retail Ground, or Package Services prices.

\* \* \* \* \*

**505 Return Services**

\* \* \* \* \*

**3.0 Merchandise Return Service  
(MRS)**

\* \* \* \* \*

**3.7 Additional Standards for USPS  
Return Services**

\* \* \* \* \*

**3.7.4 Postage**

*[Revise the first sentence of 3.7.4 to read as follows:]*

Postage is calculated based on the weight of the parcel and zone, except for First-Class Package Return Service, for which postage is based on the weight of the parcel. \* \* \*

\* \* \* \* \*

**3.7.5 Description**

*[Revise the text of 3.7.5 to read as follows:]*

Priority Mail Return Service, First-Class Package Return Service, and Ground Return Service provide return service options to customers who meet the applicable standards in 3.0. Except for restricted material described in Publication 52, any mailable matter may be mailed using any of the USPS Return Service options. Any content that constitutes First-Class Mail matter may only be mailed using Priority Mail Return Service.

\* \* \* \* \*

**3.7.8 Additional Standards for First-  
Class Package Return Service**

*[Delete the second sentence of 3.7.8.]*

\* \* \* \* \*

**4.0 Parcel Return Service****4.1 Prices and Fees**

\* \* \* \* \*

**4.1.2 Parcel Return Service Prices**

*[Revise the first sentence in the introductory text of 4.1.2 to read as follows:]*

Parcel Return Service prices are based on the price that applies to the weight increment of each addressed piece, and on the designated return facility, RDU or RSCF. \* \* \*

\* \* \* \* \*

*[Revise the first sentence of item b to read as follows:]*

b. Balloon and Oversized Prices: RSCF parcels that weigh less than 20 pounds but measure more than 84 inches in combined length and girth are charged the applicable price for a 20-pound parcel (balloon price). \* \* \*

\* \* \* \* \*

*[Delete item c in its entirety.]*

**4.1.3 Postage**

*[Revise the introductory text of 4.1.3 to read as follows:]*

There are two PRS price categories:

\* \* \* \* \*

*[Delete item c in its entirety.]*

*[Delete 4.1.4, Standard Post Prices, in its entirety.]*

**4.2 Basic Standards****4.2.1 Description**

*[Revise the text of 4.2.1 to read as follows:]*

Parcel Return Service (PRS) applies to parcels that are picked up in bulk by authorized permit holders or their agents. Permit holders guarantee payment of postage for all parcels mailed with a PRS label. By providing an approved PRS label to its customers, the merchant or other party designates the permit holder identified on the label as their agent for receipt of mail bearing that label, and authorizes the USPS to provide that mail to the permit holder or its designee. PRS permit holders also may retrieve parcels at one or more designated return sectional center facilities (RSCFs) or designated return delivery units (RDUs). Payment for parcels returned under PRS is deducted from a separate advance deposit (postage-due) account funded through the Centralized Account Processing System (CAPS). The permit holder must be authorized to use eVS (see 705.2.9).

\* \* \* \* \*

**4.2.9 Pickup Schedule and Location**

*[Revise the second sentence in the introductory text of 4.2.9 to read as follows:]*

\* \* \* If the permit holder (or agent) has existing appointments to deliver Parcel Select parcels to destination facilities and those facilities are one of the designated RSCFs or designated RDUs, those appointments can be used for retrieving PRS parcels at the same time. \* \* \*

\* \* \* \* \*

*[Delete item a and renumber items b through d as items a through c.]*

\* \* \* \* \*

*[Delete renumbered item c.]*

\* \* \* \* \*

**4.3 Labels**

\* \* \* \* \*

**4.3.5 PRS Label Format Examples**

The following are PRS label format examples. **Note:** The ZIP Code 56999 appears in each example for demonstration purposes only.

*[Replace the RNDC label example in items a and b with RSCF/RDU labels.]*

\* \* \* \* \*

**507 Mailer Services****1.0 Treatment of Mail**

\* \* \* \* \*

**1.5 Treatment for Ancillary Services  
by Class of Mail**

\* \* \* \* \*

**1.5.4 Retail Ground, Package  
Services, and Parcel Select**

*[Revise the introductory text of 1.5.4 to read as follows:]*

Undeliverable-as-addressed (UAA) Retail Ground, Package Services, and Parcel Select (see 1.5.3 for Parcel Select Lightweight) mailpieces are treated as described in Exhibit 1.5.4, with these additional conditions:

\* \* \* \* \*

*[Delete item g in its entirety.]*

\* \* \* \* \*

**Exhibit 1.5.4 Treatment of  
Undeliverable Standard Post, Package  
Services, and Parcel Select**

\* \* \* \* \*

**“Address Service Requested”**

*Shipper Paid Forwarding/Return Option*  
1

\* \* \* \* \*

If change-of-address order on file:

*[Revise the first bullet under “If change-of-address order on file” to read as follows:]*

- Months 1 through 12: Parcel forwarded. Forwarding postage is

charged to the mailer as follows; at the applicable Retail Ground or Package Services single-piece price or the Parcel Select Ground price plus the ACS & Shipper Paid Forward/Return additional service fee. Separate notice of new address provided (electronic ACS fee charged).

\* \* \* \* \*

Shipper Paid Forwarding/Return Option 2

\* \* \* \* \*

If change-of-address order on file: [Revise the first bullet under "If change-of-address order on file" to read as follows:]

• Months 1 through 12: Parcel forwarded. Forwarding postage is charged to the mailer as follows; at the applicable Retail Ground or Package Services single-piece price or the Parcel Select Ground price plus the ACS & Shipper Paid Forward/Return additional service fee. Separate notice of new address provided (electronic ACS fee charged).

\* \* \* \* \*

Shipper Paid Forwarding/Return Option 3

If no change-of-address order on file: [Revise the text under "If no change-of-address order on file" to read as follows:]

Piece returned with reason for nondelivery attached; Return postage is charged to the mailer as follows: at the Retail Ground or Package Services single-piece price, or the Parcel Select Ground price plus the ACS & Shipper Paid Forward/Return additional service fee. Separate notice provided (electronic ACS fee is charged).

If change-of-address order on file: [Revise the first bullet under "If change-of-address order on file" to read as follows:]

• Months 1 through 12: Parcel forwarded. Forwarding postage is charged to the mailer as follows: at the Retail Ground or Package Services single-piece price or the Parcel Select Ground price plus the ACS & Shipper Paid Forward/Return additional service fee. Separate notice of new address provided (electronic ACS fee is charged).

\* \* \* \* \*

"Change Service Requested"

(For Shipper Paid Forwarding/Return participants via ACS only)

\* \* \* \* \*

If change-of-address order on file: [Revise the first bullet under "If change-of-address order on file" to read as follows:]

• Months 1 through 12: Parcel forwarded; postage due charged to the mailer as follows: at the Retail Ground or Package Services single-piece price for the specific class of mail or the Parcel Select Ground price plus the ACS & Shipper Paid Forward/Return additional service fee; separate notice of new address provided (electronic ACS fee charged).

\* \* \* \* \*

1.6 Attachments and Enclosures

\* \* \* \* \*

1.6.3 Package Services and Parcel Select

Undeliverable, unendorsed mailpieces with a First-Class Mail attachment or enclosure are forwarded or returned as follows:

[Revise the text of item a to read as follows:]

a. Parcel Select at the Parcel Select Ground price plus the additional service fee.

\* \* \* \* \*

508 Recipient Services

\* \* \* \* \*

7.0 Hold For Pickup

7.1 Fees and Postage

7.1.1 Postage Payment Methods

[Revise the introductory text of 7.1.1 to read as follows:]

Hold For Pickup service is available for the mail classes listed under 7.2.2, when postage is paid by:

\* \* \* \* \*

7.2 Basic Information

\* \* \* \* \*

7.2.2 Basic Eligibility

[Revise the introductory text of 7.2.2 to read as follows:]

Hold For Pickup service is available at retail Post Office locations for Priority Mail Express presented under 113.4.2 or 113.4.3, and for Priority Mail using Click-N-Ship. It is also available with commercial mailings of Priority Mail Express presented under 213.4.2. or 213.4.3, Priority Mail, First-Class Package Service, Parcel Select Ground, Parcel Select Lightweight, and Bound Printed Matter parcels, when:

\* \* \* \* \*

[Revise the first sentence of item b to read as follows:]

b. For electronic option, mailers establish an electronic link with USPS to exchange acceptance and delivery data. \* \* \*

\* \* \* \* \*

600 Basic Standards for All Mailing Services

601 Mailability

\* \* \* \* \*

6.0 Mailing Containers—Special Types of Envelopes and Packaging

\* \* \* \* \*

[Delete 6.2, Critical Mail Envelopes, and renumber 6.3 through 6.6 as 6.2 through 6.5.]

\* \* \* \* \*

602 Addressing

1.0 Elements of Addressing

\* \* \* \* \*

1.5 Return Addresses

\* \* \* \* \*

1.5.3 Required Use of Return Addresses

The sender's domestic return address must appear legibly on:

\* \* \* \* \*

[Revise item e to read as follows:]

e. Priority Mail.

\* \* \* \* \*

5.0 Move Update Standards

5.1 Basic Standards

[Revise the second sentence in the introductory text of 5.1 to read as follows:]

\* \* \* Each address, except for mail bearing an alternative address format (under 3.0), in a mailing at commercial First-Class Mail presorted or automation prices, Standard Mail, or Parcel Select Lightweight prices is subject to the Move Update standard and must meet these requirements:

\* \* \* \* \*

[Revise the text of item b to read as follows:]

b. The Move Update standard is met when an address used on a mailpiece in a mailing at any class of mail is updated under 5.2, and the same address is used in a First-Class Mail, Standard Mail, or Parcel Select Lightweight mailing within 95 days after the address has been updated.

5.2 USPS-Approved Methods

The following methods are authorized for meeting the Move Update standard:

\* \* \* \* \*

[Revise the first sentence of item d to read as follows:]

d. For First-Class Mail only: Mailer Move Update Process Certification and USPS-approved alternative methods for mailers with legitimate restrictions on incorporating USPS-supplied change-of-

address information into their mailing lists. \* \* \*

\* \* \* \* \*

## 6.0 ZIP Code Accuracy Standards

### 6.1 Basic Standards

*[Revise the introductory text of 6.1 to read as follows:]*

Except for mail bearing a simplified address, addresses used on pieces in a mailing at all commercial First-Class Mail, nonbarcoded presorted Periodicals, Standard Mail, Parcel Select Lightweight, and Bound Printed Matter presorted and carrier route prices are subject to the ZIP Code accuracy standard and must meet these requirements:

\* \* \* \* \*

### 6.04 Postage Payment Methods

\* \* \* \* \*

### 4.0 Postage Meters and PC Postage Products (“Postage Evidencing Systems”)

#### 4.1 Basic Information

\* \* \* \* \*

#### 4.1.5 Authorized Classes of Mail

*[Revise the text of 4.1.5 to read as follows:]*

Mailers may use postage evidencing systems to affix or apply indicia on any class of mail except Periodicals and Bound Printed Matter. PC Postage products may be used for Retail Ground only by USPS-Approved Shippers.

\* \* \* \* \*

### 5.0 Permit Imprint (Indicia)

\* \* \* \* \*

### 5.3 Indicia Design, Placement, and Content

\* \* \* \* \*

*[Revise the heading and text of 5.3.6 to read as follows:]*

#### 5.3.6 Priority Mail Express, Priority Mail, First-Class Mail, and First-Class Package Service Format

A permit imprint indicia on Priority Mail Express, Priority Mail, First-Class Mail, or First-Class Package Service mailpieces must show “Priority Mail Express,” “Priority Mail” (or “Priority”), “First-Class Mail,” or “First-Class Package” (or “First-Class Pkg”) as applicable; “U.S. Postage Paid”; city and state; and permit number. If the Electronic Verification System (eVS) is used under 705.2.9, the marking “eVS” (or the alternative “e-VS” or “E-VS”) must appear directly below the permit number. The “Priority Mail Express,” or “Priority Mail” (or “Priority”), marking may be omitted when using USPS-

provided Priority Mail Express or Priority Mail containers. The indicia may show the mailing date, amount of postage paid, or the number of ounces for which postage is paid. The ZIP Code of the permit holder may be shown directly after the state name or in a separate inscription reading “ZIP Code 00000,” when that ZIP Code does not create uncertainty about the permit holder’s correct address or permit number. Instead of printing the city and state of mailing in the indicia, the mailer may print “Mailed From ZIP Code,” followed by the 5-digit ZIP Code assigned to the postmaster of the mailing office. The indicia may also include required price markings.

\* \* \* \* \*

## 7.0 Computing Postage

### 7.1 General Standards

#### 7.1.1 Determining Single-Piece Weight for Retail and Commercial Mail

*[Revise the third sentence of 7.1.1 to read as follows:]*

\* \* \* Express all single-piece weights in decimal pounds rounded off to two decimal places for the following mailpieces: Priority Mail Express, Priority Mail, Parcel Select, Bound Printed Matter, Media Mail, and Library Mail prices. \* \* \*

\* \* \* \* \*

### 12.0 Scan Based Payment

#### 12.1 Basic Information

\* \* \* \* \*

#### 12.1.2 Eligibility

*[Revise the second sentence of 12.1.2 to read as follows:]*

\* \* \* Returns include Ground Return Service, First-Class Package Return Service, Priority Mail Return Service, and Parcel Return Service shipments. \* \* \*

\* \* \* \* \*

## 700 Special Standards

\* \* \* \* \*

### 705 Advanced Preparation and Special Postage Payment Systems

\* \* \* \* \*

## 6.0 Combining Mailings of Standard Mail, Package Services, and Parcel Select Parcels

\* \* \* \* \*

*[Revise the heading of 6.3 to read as follows:]*

## 6.3 Combining Parcels—DSCF and DDU Prices

### 6.3.1 Qualification

Combination requirements for specific discounts and prices are as follows:

*[Delete item a and renumber items b and c as items a and b.]*

\* \* \* \* \*

### 6.3.2 Preparation and Prices

Combined parcels must be prepared as follows:

\* \* \* \* \*

*[Delete item c and renumber item d as item c.]*

\* \* \* \* \*

## 8.0 Preparing Pallets

\* \* \* \* \*

### 8.4 Pallet Boxes

#### 8.4.1 Use

*[Revise the text of 8.4.1 to read as follows:]*

A mailer may use pallet boxes constructed of single-, double-, or triple-wall corrugated fiberboard placed on pallets to hold sacks or parcels. Pallet boxes must protect the mail and maintain the integrity of the pallet loads throughout transportation, handling, and processing. Single-wall corrugated fiberboard may be used only for light loads (such as lightweight parcels) that do not require transportation by the USPS beyond the entry office, or for Parcel Select DSCF and DDU price mail. Mailers must supply their own pallet boxes. The base of the boxes must measure approximately 40 by 48 inches.

#### 8.4.2 Height

*[Delete the last sentence of 8.4.2.]*

\* \* \* \* \*

### 8.5 General Preparation

\* \* \* \* \*

#### 8.5.2 Required Preparation

*[Revise the introductory text of 8.5.2 to read as follows:]*

The following standards apply to Periodicals, Standard Mail, Parcel Select, and Package Services, except Parcel Select mailed at DSCF and DDU prices:

\* \* \* \* \*

#### 8.5.3 Minimum Load

The following minimum load standards apply to mail prepared on pallets:

*[Revise the introductory text of item a to read as follows:]*

a. For Periodicals, Standard Mail, Parcel Select, and Package Services

(except for Parcel Select mailed at DSCF and DDU prices):

\* \* \* \* \*

[Revise the text of item b to read as follows:]

b. Parcel Select mailed at DSCF and DDU prices. A minimum load for the price claimed may be stated in terms of weight, combined piece minimum and weight, or minimum height. Mail entered at the Parcel Select DSCF prices and prepared directly on pallets or in pallet boxes on pallets must be prepared under either a minimum height requirement or under one of two options requiring a minimum number of pieces and pounds per pallet. There is no minimum weight requirement for an SCF pallet containing 5-digit scheme and 5-digit sacks prepared for the DSCF price. There are no minimums for the Parcel Select DDU price.

**8.5.4 Minimum Height of Mail**

[Revise the introductory text of 8.5.4 to read as follows:]

The definitions of the minimum height of mail used to qualify for DSCF Parcel Select prices are as follows:

\* \* \* \* \*

[Delete 8.19, Parcel Select—Origin Network Distribution Center (ONDC) Presort Discount, in its entirety and renumber 8.20 through 8.22 as 8.19 through 8.21.]

\* \* \* \* \*

**18.0 Priority Mail Express Open and Distribute and Priority Mail Open and Distribute**

\* \* \* \* \*

**18.1 Prices and Fees**

\* \* \* \* \*

**18.1.5 Payment Method**

Postage payment methods are as follows:

[Revise the first sentence in item b to read as follows:]

b. Priority Mail Express postage may be paid under any of the options listed in 214.1.1. \* \* \*

[Revise the first sentence in item c to read as follows:]

c. Priority Mail postage may be paid under any of the options listed in 224.1.1.1. \* \* \*

\* \* \* \* \*

**18.5 Preparation**

**18.5.1 Containers for Expedited Transport**

Acceptable containers for expedited transport are as follows:

\* \* \* \* \*

[Revise the text of item c to read as follows:]

c. A Priority Mail Express or Priority Mail Open and Distribute shipment destined to a DDU may be contained in USPS-provided Priority Mail Express Flat Rate envelopes using the applicable label in 18.5.3a, or Priority Mail Flat Rate Envelopes and boxes using the applicable label in 18.5.3b.

\* \* \* \* \*

**21.0 Optional Combined Parcel Mailings**

\* \* \* \* \*

**21.2.2 Price Application**

Apply prices based on the criteria in 200 and the following standards:

\* \* \* \* \*

[Revise the text of item e to read as follows:]

e. Parcel Select prices are based on the destination entry for pieces in 5-digit, 3-digit, ADC, or NDC containers.

\* \* \* \* \*

**708 Technical Specifications**

**1.0 Standardized Documentation for First-Class Mail, Periodicals, Standard Mail, and Flat-Size Bound Printed Matter**

\* \* \* \* \*

**1.3 Price Level Column Headings**

The actual name of the price level (or abbreviation) is used for column headings required by 1.2 and shown below:

\* \* \* \* \*

b. Presorted First-Class Mail, barcoded and nonbarcoded Periodicals flats, nonbarcoded Periodicals letters, and machinable and nonmachinable Standard Mail:

[Revise the table under item b to read as follows:]

Price	Abbreviation
Presorted [First-Class Mail letters/cards, flats, and parcels].	Presort.
5-Digit [all Standard Mail and Periodicals letters].	5D.
FSS [Periodicals flats, Standard Mail flats].	SD.
3-Digit [all Standard Mail and Periodicals letters].	3D.
SCF [for Standard Mail parcels].	SCF.
AADC [Standard Mail machinable letters].	AB.
ADC [Standard Mail nonmachinable letters, flats, and irregular parcels, and all Periodicals].	AD.
Basic [In-County Periodicals]	BS.
Mixed AADC [Standard Mail machinable letters].	MB.

Price	Abbreviation
Mixed ADC [Standard Mail nonmachinable letters, flats, irregular parcels; and all Periodicals].	MD.
NDC [Standard Mail machinable parcels and Marketing parcels 6 ounces and over].	NDC.
Mixed NDC [Standard Mail machinable parcels and Marketing parcels 6 ounces and over].	MNDC.
Firm [Outside-County Periodicals].	FB.

\* \* \* \* \*

**6.0 Standards for Barcoded Tray Labels, Sack Labels, and Container Placards**

\* \* \* \* \*

**6.2 Specifications for Barcoded Tray and Sack Labels**

\* \* \* \* \*

**6.2.4 3-Digit Content Identifier Numbers**

\* \* \* \* \*

**Exhibit 6.2.4 3-Digit Content Identifier Numbers**

\* \* \* \* \*

**Priority Mail Open and Distribute**

\* \* \* \* \*

[Delete the "First-Class Package Service, Parcels" section in its entirety.]

\* \* \* \* \*

**First-Class Mail**

\* \* \* \* \*

[Delete the "FC Parcels—Presorted" section in its entirety.]

\* \* \* \* \*

**7.0 Optional Endorsement Lines (OELs)**

\* \* \* \* \*

**7.2.5 ZIP Code Information**

\* \* \* \* \*

**Exhibit 7.2.5 OEL Labeling Lists**

\* \* \* \* \*

**First-Class Mail**

\* \* \* \* \*

[Delete the "Parcels" line in its entirety from the "First-Class Mail" section.]

\* \* \* \* \*

**Index and Appendices**

**A**

\* \* \* \* \*

**Address Quality Standards, Parcels**

\* \* \* \* \*

## Move Update

[Delete DMM reference 283.3.5]

\* \* \* \* \*

**B**

\* \* \* \* \*

**Bundles of Parcels**

\* \* \* \* \*

## sacks

[Delete the “First-Class Package Service” line under “sacks”.]

\* \* \* \* \*

**D**

\* \* \* \* \*

**Documentation**

\* \* \* \* \*

## commercial parcels

[Delete the “First-Class Package Service” line under “commercial parcels”.]

\* \* \* \* \*

**E**

\* \* \* \* \*

**Entry**

\* \* \* \* \*

## commercial parcels

[Revise “First-Class Mail” to read as “First-Class Package Service”.]

\* \* \* \* \*

**F**

\* \* \* \* \*

**First-Class Package Service, Commercial Parcels**

[Revise the index of “First-Class Package Service”, commercial parcels to read as follows:]

combined with other classes of mail, 703.9.0

computing postage, 283.1.1

content standards, 283.2.0

deposit of, 286.1.0

documentation, 284.3.0

eligibility standards, 283

incidental enclosure with another class of mail, 703.9.5

mail preparation, 285

markings required on each mailpiece general, 202.1.0

postage payment methods, 284

postage statements, 284.2.0

price eligibility, 283.4.0

size, 201.8.3

surcharge, 283.1.4

undeliverable mail, 507.1.5.1

weight, 201.8.3.1

ZIP Code accuracy, 283.3.5

\* \* \* \* \*

**L****Labels**

\* \* \* \* \*

## sacks and trays

\* \* \* \* \*

## commercial parcels

[Delete the “First-Class Package Service” line under “commercial parcels”.]

\* \* \* \* \*

**M**

\* \* \* \* \*

**Mailing Fees**

\* \* \* \* \*

## commercial parcels

[Delete the “First-Class Package Service” line under “commercial parcels”.]

\* \* \* \* \*

**Move Update Standard**

[Delete DMM reference 283.3.5 from the “commercial parcels” line.]

\* \* \* \* \*

**P**

\* \* \* \* \*

**Parcel Select**

\* \* \* \* \*

## mail preparation

[Delete the “NDC Presort prices on pallets” and “ONDC Presort prices” lines under “mail preparation”.]

\* \* \* \* \*

## price eligibility

[Delete the “NDC Presort prices” and “ONDC Presort prices” lines under “price eligibility”.]

\* \* \* \* \*

**Presort Verification**

\* \* \* \* \*

## commercial parcels

[Delete the “First-Class Package Service” line under “commercial parcels”.]

\* \* \* \* \*

**Priority Mail**

\* \* \* \* \*

[Delete the “Critical Mail” line under “Priority Mail”.]

\* \* \* \* \*

**S****Sacks**

[Delete the “First-Class Package Service” line under “sacks”.]

\* \* \* \* \*

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

**Stanley F. Mires,**

Attorney, Federal Compliance.

[FR Doc. 2015–26920 Filed 10–23–15; 8:45 am]

**BILLING CODE 7710–12–P**

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 62**

[EPA–R02–OAR–2015–0509; FRL–9936–09–Region 2]

**Approval and Promulgation of State Plans for Designated Facilities; New York**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency is approving a request from the State of New York that EPA withdraw its approval of a provision of the New York State plan that implements and enforces the Emission Guidelines for existing sewage sludge incineration units. This action withdraws the EPA’s approval of a provision of the State sewage sludge incineration plan allowing for affirmative defenses of Clean Air Act violations in the case of malfunctions. No other provision in the State plan is affected by this action.

**DATES:** This rule is effective on November 25, 2015.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA–R02–OAR–2015–0509. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) Web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either at [www.regulations.gov](http://www.regulations.gov) or at the Environmental Protection Agency, Region 2 Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866. The EPA requests, if at all possible, that you contact the individual in the **FOR FURTHER INFORMATION CONTACT** section to view the docket. The Regional Office’s official hours of business are Monday through Friday, 8:30 a.m. to 4 p.m., excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:**

Anthony (Ted) Gardella ([gardella.anthony@epa.gov](mailto:gardella.anthony@epa.gov)), Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 1007–1866, (212) 637–3892.

**SUPPLEMENTARY INFORMATION:****I. What action is the EPA taking?**

The EPA is approving a request from the State of New York that EPA

withdraw its approval of an affirmative defense provision in New York State's sewage sludge incineration (SSI) plan, based on a letter submitted by New York on January 27, 2015. New York State submitted the State SSI plan for EPA approval on July 1, 2013 to fulfill the requirements of sections 111(d) and 129 of the Clean Air Act (CAA). The EPA approved the proposed State SSI plan on June 11, 2014 (79 FR 33456). The State SSI plan adopts and implements the emission guidelines (EG) set forth at Title 40 part 60 subpart MMMM of the Code of Federal Regulations (CFR) and is applicable to existing SSI units and establishes air emission limits and other requirements. Existing SSI units are units constructed on or before October 14, 2010.

## II. Which provision of the State SSI plan is EPA withdrawing approval of?

New York State requested that the EPA withdraw its approval of a provision in the State SSI plan that allows for an affirmative defense by an owner/operator of an affected SSI unit for violations of air emissions or other requirements of the State's plan in the event of malfunction(s) of the SSI unit. The EPA's withdrawal of its prior approval, once finalized and effective, results in the removal of the affirmative defense provision from the federally-enforceable State SSI plan while maintaining the federal enforceability of the remainder of the State SSI plan for covered SSI units located in New York State.

New York's State SSI plan adopted by reference all the applicable requirements of the EPA's SSI EG, including the affirmative defense provisions at § 60.5181, into its State plan at Part 200 of Title 6 of the New York Code of Rules and Regulations (6NYCRR) of the State of New York, entitled "General Provisions."

For further details concerning today's action, the reader is referred to the EPA's proposed rule published in the **Federal Register** on August 24, 2015 (80 FR 51170).

## III. What comments were received on the proposed approval and how has the EPA responded to them?

There were no comments received on EPA's proposed rulemaking (80 FR 51170, August 24, 2015) regarding the EPA's withdrawal of its prior approval of the affirmative defense provision in New York State's SSI plan. The 30-day public comment period on EPA's proposed approval ended on September 23, 2015.

## IV. What is the EPA's Conclusion?

The EPA has evaluated New York's January 27, 2015 request for consistency with the CAA, as well as the EPA's regulations and policy. Therefore, the EPA is approving to withdraw its approval of the affirmative defense provision of New York's State SSI plan, which the EPA approved on June 11, 2014 (79 FR 33456) as part of New York's sections 111(d) and 129 State SSI plan for existing sewage sludge incineration units. No other provisions in the New York State SSI plan is affected by this approval.

The EPA has determined that New York State's SSI plan will continue to meet all the applicable approval criteria if EPA withdraws its approval of the affirmative defense provision. First, the removal of the affirmative defense provision is consistent with the DC Circuit's decision in *Natural Resources Defense Council v. Environmental Protection Agency*, 749 F3d 1055 (D.C. Cir. April 18, 2014), as described in the EPA's proposed rulemaking (80 FR 51170, August 24, 2015). Second, a state plan must be at least as protective as the emissions guidelines promulgated by the EPA, and the removal of the affirmative defense provision from the approved state plan does not render the plan less protective, as it removes a potential defense to a violation resulting from a malfunction.

## V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a 111(d)/129 plan submission that complies with the provisions of the Act and applicable Federal regulations. 40 CFR 62.04. Thus, in reviewing 111(d)/129 plan submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive 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 Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The 111(d)/129 plan is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian Nation Land, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65FR67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 28, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time

within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

#### List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Aluminum, Fertilizers, Fluoride, Intergovernmental relations, Paper and paper products industry, Phosphate, Reporting and recordkeeping requirements, Sulfur oxides, Sulfur acid plants, Waste treatment and disposal.

Dated: October 14, 2015.

**Judith A. Enck,**

*Regional Administrator, Region 2.*

40 CFR part 62 is amended as follows:

#### PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### Subpart HH—New York

■ 2. Section 62.8108 is amended by adding paragraphs (d) and (e) to read as follows:

##### § 62.8108 Identification of plan.

\* \* \* \* \*

(d) On January 27, 2015, the New York State Department of Environmental Conservation (NYSDEC) submitted to the Environmental Protection Agency (EPA) a request to revise its section 111(d)/129 plan for implementation and enforcement of 40 CFR part 60, subpart MMMM—Emission Guidelines and Compliance Times for Existing Sewage Sludge Incineration (SSI) Units submitted on July 1, 2013 and approved by the EPA on June 11, 2014 (79 FR 33456). NYSDEC's January 27, 2015 revision consisted of a request that EPA withdraw its June 11, 2013 approval of the affirmative defense provision as part of its State SSI plan, submitted to EPA for approval on July 1, 2013.

(e) The effective date of EPA's approval of NYSDEC's revised plan for existing sewage sludge incineration units is November 25, 2015.

[FR Doc. 2015–27166 Filed 10–23–15; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### 44 CFR Part 67

[Docket ID FEMA–2015–0001]

#### Final Flood Elevation Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final rule.

**SUMMARY:** Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

**DATES:** The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated in the table below.

**ADDRESSES:** The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) [Luis.Rodriguez3@fema.dhs.gov](mailto:Luis.Rodriguez3@fema.dhs.gov).

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final rule 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 proof Flood Insurance Study and FIRM available at the address cited below for each community. The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

*National Environmental Policy Act.* This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

*Regulatory Flexibility Act.* As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

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

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

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

#### List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Dated: October 8, 2015.

**Roy E. Wright,**

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

Accordingly, 44 CFR part 67 is amended as follows:

#### PART 67—[AMENDED]

■ 1. The authority citation for part 67 continues to read as follows:

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

##### § 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:



Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ^ Elevation in meters (MSL) Modified	Communities affected
<b>St. Charles County, Missouri, and Incorporated Areas</b> <b>Docket Nos.: FEMA-B-1062 and B-1167</b>			
Baltic Creek .....	At the confluence with Dardenne Creek .....	+470	City of Cottleville, City of St. Peters, City of Weldon Spring, Unincorporated Areas of St. Charles County.
Blanchette Creek (Backwater from Missouri River).	Approximately 0.7 mile upstream of the confluence with Tributary 7	+492	City of St. Charles, Unincorporated Areas of St. Charles County.
	Just downstream of Katy Trail/Abandoned Railroad .....	+455	
Boschert Creek .....	At the confluence with the Missouri River .....	+455	City of St. Charles, Unincorporated Areas of St. Charles County.
	At the confluence with Cole Creek .....	+441	
Cole Creek .....	Approximately 0.6 mile upstream of Sibley Street .....	+532	City of St. Charles.
	Approximately 0.4 mile upstream of the confluence with Boschert Creek.	+443	
Crooked Creek .....	Approximately 800 feet upstream of Graystone Drive .....	+529	City of Cottleville, City of O'Fallon, City of Weldon Spring, Unincorporated Areas of St. Charles County.
	At the confluence with Dardenne Creek .....	+475	
Crystal Springs Creek (Backwater from Missouri River).	Approximately 0.7 mile upstream of I-64 .....	+574	City of St. Charles, Unincorporated Areas of St. Charles County.
	At the confluence with the Missouri River .....	+457	
Cunningham Branch .....	Approximately 871 feet upstream of South River Road .....	+457	City of O'Fallon, Unincorporated Areas of St. Charles County.
	At the confluence with Dardenne Creek .....	+535	
Dardenne Creek .....	Approximately 1,250 feet upstream of State Highway D .....	+644	City of Cottleville, City of O'Fallon, City of St. Peters, Town of Dardenne Prairie, Unincorporated Areas of St. Charles County.
	Approximately 400 feet downstream of Norfolk Southern Railroad ....	+444	
Duckett Creek (Overflow from Missouri River).	Approximately 2.3 miles upstream of Oberhelman Road .....	+748	Unincorporated Areas of St. Charles County.
	At the confluence with the Missouri River .....	+462	
East Branch Spencer Creek .....	Approximately 0.5 miles upstream of Jungs Station Road .....	+463	City of St. Peters.
	At the confluence with Spencer Creek .....	+458	
East Branch Tributary B .....	Just downstream of Boone Hills Drive .....	+503	City of Cottleville, City of O'Fallon, Unincorporated Areas of St. Charles County.
	At the confluence with Dardenne Creek .....	+480	
East Cole Creek .....	Approximately 150 feet upstream of State Highway K .....	+525	City of St. Charles.
	At the confluence with Cole Creek .....	+457	
Femme Osage Creek (Backwater from Missouri River).	Approximately 600 feet upstream of Canary Lane .....	+478	Unincorporated Areas of St. Charles County.
	Approximately 0.4 miles downstream of State Highway 94 .....	+476	
Kraut Run .....	Approximately 1.4 miles downstream of Defiance Road .....	+476	Unincorporated Areas of St. Charles County.
	At the confluence with Dardenne Creek .....	+506	
Lake Sainte Louise .....	Approximately 1,000 feet upstream of Wilson Road .....	+607	City of Lake St. Louis.
	Entire shoreline within community .....	+546	
Little Dardenne Creek .....	At the confluence with Dardenne Creek .....	+554	Unincorporated Areas of St. Charles County.
Mississippi River .....	Approximately 0.9 mile upstream of Morrison Lane .....	+719	City of O'Fallon, City of Portage Des Sioux, City of St. Charles, City of St. Paul, City of St. Peters, Town of West Alton, Unincorporated Areas of St. Charles County.
	At the St. Charles County, Missouri/St. Louis County, Missouri/Madison County, Illinois county boundary, approximately 6.2 miles downstream of Melvin Price Lock and Dam.	+434	
Missouri River .....	At the St. Charles County/Lincoln County boundary, approximately 3.0 miles upstream of confluence with Peruue Creek.	+444	City of St. Charles, City of Weldon Spring, Town of Augusta, Unincorporated Areas of St. Charles County.
	At the St. Charles County, Missouri/St. Louis County, Missouri/Madison County, Illinois county boundary, approximately 7.4 miles downstream of the Lewis Bridge.	+434	
	Near the St. Charles County/Warren County boundary, approximately 22.3 miles upstream of the Daniel Boone Bridge.	+492	

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ^ Elevation in meters (MSL) Modified	Communities affected
Oday Creek .....	At the confluence with Dardenne Creek .....	+505	City of Lake St. Louis, City of O'Fallon, City of St. Charles, Unincorporated Areas of St. Charles County.
Old Dardenne Creek .....	Approximately 425 feet upstream of State Highway N .....	+587	
	At the confluence with Dardenne Creek .....	+486	Town of Dardenne Prairie, City of O'Fallon, City of St. Charles, Unincorporated Areas of St. Charles County.
Peruque Creek .....	Approximately 350 feet upstream of U.S. Route 40/61 .....	+502	
	Approximately 0.3 mile downstream of State Highway Z .....	+530	City of Foristell, City of Wentzville, Unincorporated Areas of St. Charles County.
Peruque Creek Tributary 12 .....	Approximately 1.3 miles upstream of State Highway T .....	+630	
	At the confluence with Peruque Creek .....	+471	City of St. Paul, Unincorporated Areas of St. Charles County.
Peruque Creek Tributary 14 .....	Approximately 0.4 mile upstream of Meadow Farm Lane .....	+527	
	Approximately 0.2 mile upstream of the confluence with Peruque Creek.	+464	City of O'Fallon, Unincorporated Areas of St. Charles County.
Peruque Creek Tributary 15 .....	Approximately 1,000 feet upstream of Civic Park Drive .....	+512	
	Approximately 900 feet upstream of the confluence with Peruque Creek.	+464	City of O'Fallon.
Peruque Creek Tributary 2 .....	Approximately 1,300 feet upstream of Main Street .....	+507	
	At the confluence with Peruque Creek .....	+613	City of Foristell, Unincorporated Areas of St. Charles County.
Peruque Creek Tributary 8 .....	Approximately 600 feet upstream of State Highway T .....	+734	
	Approximately 1.0 mile upstream of the confluence with Peruque Creek.	+505	City of Lake St. Louis, City of Wentzville.
Peruque Creek Tributary 9 .....	Approximately 0.6 mile upstream of I-70 .....	+546	
	Approximately 1.0 mile upstream of the confluence with Peruque Creek.	+505	City of Lake St. Louis, Unincorporated Areas of St. Charles County.
Sandfort Creek .....	Approximately 0.4 mile upstream of Henke Road .....	+539	
	Just downstream of Norfolk Southern Railroad .....	+442	City of St. Charles, Unincorporated Areas of St. Charles County.
Schote Creek .....	Approximately 350 feet downstream of Muegge Road .....	+497	
	At the confluence with Dardenne Creek .....	+481	City of O'Fallon, Town of Dardenne Prairie, Unincorporated Areas of St. Charles County.
Spencer Creek .....	Approximately 1.6 miles upstream of U.S. Route 40/61 .....	+583	
	Approximately 365 feet upstream of the railroad .....	+444	City of St. Peters, Unincorporated Areas of St. Charles County.
Taylor Branch (Backwater from Missouri River).	Approximately 1,200 feet upstream of Millwood Drive .....	+526	
	At the confluence with the Missouri River .....	+460	City of St. Charles, Unincorporated Areas of St. Charles County.
Tributary A .....	Approximately 0.6 miles upstream of South River Road .....	+460	
	At the confluence with Dardenne Creek .....	+469	City of St. Peters, Unincorporated Areas of St. Charles County.
Tributary No. 1 .....	Approximately 500 feet upstream of Starlight Drive .....	+536	
	At the confluence with Dardenne Creek .....	+464	City of St. Peters, Unincorporated Areas of St. Charles County.
Tributary No. 13 .....	Approximately 400 feet upstream of Harris Drive .....	+473	
	At the confluence with Dardenne Creek .....	+486	Town of Dardenne Prairie, City of O'Fallon.
Tributary No. 15 .....	Approximately 700 feet upstream of McClure Road .....	+508	
	At the confluence with Dardenne Creek .....	+495	Town of Dardenne Prairie, City of O'Fallon, Unincorporated Areas of St. Charles County.
Tributary No. 17 .....	Approximately 300 feet upstream of Keystone Crossing Drive .....	+567	
	Approximately 0.8 mile upstream of the confluence with Dardenne Creek.	+522	City of O'Fallon, Unincorporated Areas of St. Charles County.
Tributary No. 19 .....	Approximately 900 feet upstream of Hopewell Road .....	+895	
	Approximately 1,300 feet upstream of the confluence with Dardenne Creek.	+505	Unincorporated Areas of St. Charles County.
Tributary No. 2 .....	Approximately 2.1 miles upstream of the confluence with Dardenne Creek.	+573	
	Just upstream of Ohmes Road .....	+465	City of St. Peters.
Tributary No. 3 .....	Approximately 0.5 mile upstream of Ohmes Road .....	+478	
	At the confluence with Tributary A .....	+469	Unincorporated Areas of St. Charles County.
	Approximately 0.8 mile upstream of St. Peters-Howell Road .....	+503	

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ^ Elevation in meters (MSL) Modified	Communities affected
Tributary No. 4 .....	At the confluence with Tributary A .....	+469	City of St. Peters, Unincorporated Areas of St. Charles County.
Tributary No. 7 .....	Approximately 1,150 upstream of Woodstream Drive ..... At the confluence with Baltic Creek .....	+509 +482	City of St. Peters, City of Weldon Spring.
Tributary No. 9 .....	Approximately 0.8 mile upstream of Pitmann Hill Road ..... At the confluence with Crooked Creek .....	+504 +480	City of Weldon Spring, Unincorporated Areas of St. Charles County.
West Branch Spencer Creek .....	Approximately 0.5 mile upstream of Guthermuth Road ..... At the confluence with Spencer Creek .....	+497 +450	Unincorporated Areas of St. Charles County.
West Branch Tributary B .....	Approximately 400 feet upstream of Willott Road ..... At the confluence with East Branch Tributary B .....	+510 +489	Town of Dardenne Prairie.
West Sandfort Creek .....	Approximately 150 feet upstream of Bryan Road ..... At the confluence with Sandfort Creek .....	+622 +450	City of St. Charles, Unincorporated Areas of St. Charles County.
	Approximately 1,400 feet upstream of Harry S. Truman Boulevard ...	+459	

\* National Geodetic Vertical Datum.  
 + North American Vertical Datum.  
 # Depth in feet above ground.  
 ^ Mean Sea Level, rounded to the nearest 0.1 meter.

**ADDRESSES**

**City of Cottleville**

Maps are available for inspection at City Hall, 5490 5th Street, Cottleville, MO 63338.

**City of Foristell**

Maps are available for inspection at City Hall, 121 Mulberry Street, Foristell, MO 63348.

**City of Lake St. Louis**

Maps are available for inspection at City Hall, 200 Civic Center Drive, Lake St. Louis, MO 63367.

**City of O'Fallon**

Maps are available for inspection at City Hall, 100 North Main Street, O'Fallon, MO 63366.

**City of Portage Des Sioux**

Maps are available for inspection at the County Administration Building, 201 North 2nd Street, Room 420, St. Charles, MO 63301.

**City of St. Charles**

Maps are available for inspection at City Hall, 200 North 2nd Street, St. Charles, MO 63301.

**City of St. Paul**

Maps are available for inspection at City Hall, 2300 St. Paul Road, St. Paul, MO 63366.

**City of St. Peters**

Maps are available for inspection at City Hall, 1 St. Peters Centre Boulevard, St. Peters, MO 63376.

**City of Weldon Spring**

Maps are available for inspection at City Hall, 5401 Independence Road, Weldon Spring, MO 63304.

**City of Wentzville**

Maps are available for inspection at City Hall, 310 West Pearce Boulevard, Wentzville, MO 63385.

**Town of Dardenne Prairie**

Maps are available for inspection at Town Hall, 2032 Hanley Road, Dardenne Prairie, MO 63368.

**Town of West Alton**

Maps are available for inspection at 201 North 2nd Street, Room 420, St. Charles, MO 63301.

**Unincorporated Areas of St. Charles County**

Maps are available for inspection at the County Administration Building, 201 North 2nd Street, Room 420, St. Charles, MO 63301.

**Town of Augusta**

Maps are available for inspection at Town Hall, 239 Green Street, Augusta, MO 63332.

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****46 CFR Part 15**

[Docket No. USCG–2015–0758]

RIN 1625–AC25

**Offshore Supply Vessels, Towing Vessel, and Barge Engine Rating Watches**

AGENCY: Coast Guard, DHS.

ACTION: Direct final rule.

**SUMMARY:** This direct final rule amends the Coast Guard's merchant mariner manning regulations to align them with statutory changes made by the Howard Coble Coast Guard and Maritime Transportation Act of 2014. The Act allows oilers serving on certain offshore support vessels, towing vessels, and barges to be divided into at least two watches. This change increases the sea service credit affected mariners are permitted to earn for each 12-hour period of work from one day to one and a half days.

**DATES:** This direct final rule will be effective January 25, 2016 unless the Coast Guard receives adverse comment by December 28, 2015. If an adverse comment is received, the Coast Guard will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public the rule will not take effect.

**ADDRESSES:** You may submit comments identified by docket number USCG–2015–0758 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the "Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, email or call Mr. Davis Breyer, Marine Personnel Qualifications Division (CG–OES–1), Coast Guard; email [Davis.J.Breyer@uscg.mil](mailto:Davis.J.Breyer@uscg.mil), telephone (202) 372–1445.

**SUPPLEMENTARY INFORMATION:****I. 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. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER**

**INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site's instructions. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

**II. Abbreviations**

CFR Code of Federal Regulations  
 DHS Department of Homeland Security  
 FR Federal Register  
 NPRM Notice of proposed rulemaking  
 OMB Office of Management and Budget  
 QMED Qualified Member of the Engine Department  
 RFA Regulatory Flexibility Act  
 The Secretary The Secretary of Homeland Security  
 Sec. 316 Section 316 of the Howard Coble Coast Guard and Maritime Transportation Act of 2014  
 U.S.C. United States Code

**III. Basis and Purpose***A. Basis*

The changes to 46 CFR 15.705 made by this rule are required by 46 U.S.C. 8104 as amended by Sec. 316 of the Howard Coble Coast Guard and Maritime Transportation Act of 2014 (Pub. L. 113–281, December 18, 2014). Under Title 46 of the United States Code, Sec. 2103, the Secretary of Homeland Security (the Secretary) has general authority over the merchant marine of the United States and merchant marine personnel. The Secretary delegated the authority for determining minimum manning standards to the Commandant of the Coast Guard in Department of Homeland Security Delegation No. 0170.1, paragraph 92.

*B. Purpose*

The purpose of this rule is to conform regulations to the amended statute and clarify that oilers on covered vessels are entitled to receive an equitable amount of sea service credit.

**IV. Discussion of the Rule**

The Howard Coble Coast Guard and Maritime Transportation Act of 2014, sec. 316, amended 46 U.S.C. 8104(g)(1) by allowing coal passers, firemen, oilers, and water tenders serving on offshore supply vessels, towing vessels, and barges engaged in seagoing voyages of

less than 600 miles to be divided into at least two watches. Previously, only officers and other deck crew members on those vessels were divided into two watches.

46 CFR 10.107 and 10.232(h)(2) provide in the definition of "Day" that "[o]n vessels authorized by 46 U.S.C. 8104 and 46 CFR 15.705 to operate a two-watch system, a 12-hour working day may be creditable as 1½ days of service." Regulations at 46 CFR 15.705(c)(1), however, still do not authorize mariners affected by sec. 316 to be divided into two watches. In order to align the regulations with the amended statute, this direct final rule revises 46 CFR 15.705(c)(1) by deleting the clause "(except the coal passers, firemen, oilers, and water tenders)".

Similarly, sec. 316 also updated 46 U.S.C. 8104(d) by deleting the words "coal passers, firemen, . . . and watertenders." The changes related to those terms simplify the statute. To update the corresponding regulations and align them with the revised statute, this rule also makes similar changes to 46 CFR 15.705(b).

This rule makes existing regulations consistent with the statute and clarifies the sea service credit of maritime personnel on affected vessels, which have for many years operated on a two-watch system, both on deck and in the engine room. Specifically, the revised regulations make clear that typical sea service credit for upgrades toward engineering licenses for oilers is 1½ days for each 12-hour period worked, as it is for personnel aboard the same vessels working toward deck licenses and upgrades. The effect of these changes is that all qualified members of the engine department on covered vessels are permitted to divide into two watches, and will be given proper credit for 12 hours of work in accordance with the amended statute.

Revision of our regulations without delay is necessary because misalignment between the amended statute and the corresponding regulations causes confusion, and delay could have a negative impact on the sea service credit and career advancement of oilers on affected vessels. Additionally, the Coast Guard must conform its regulations to the revised statute, and is exercising no discretion in doing so because this rule will only mirror amended statutory language. For these reasons, the rule is expected to be uncontroversial, and adverse comment is unlikely.

**V. Direct Final Rule**

A direct final rule is appropriate when a rule is noncontroversial and

unlikely to result in adverse public comment. The Coast Guard considered publishing a notice of proposed rulemaking, but is pursuing a direct final rule because it will better serve the regulated mariners and industry by correcting the misalignment between the regulations and statute more quickly. If no adverse comment is received by December 28, 2015, this rule will become effective as stated in the **DATES** section.<sup>1</sup> In that case, we will publish a document in the **Federal Register** stating that no adverse comment was received and confirming that this rule will become effective as scheduled. However, if we receive an adverse comment, we will publish a document in the **Federal Register** announcing the withdrawal of all or part of this direct final rule. If an adverse comment applies only to part of this rule (e.g., to an amendment, a paragraph, or a section) and it is possible to remove that part without defeating the purpose of this rule, we may adopt, as final, those parts of this rule on which no adverse comment was received. We will withdraw the part of this rule that was the subject of an adverse comment. If we decide to proceed with a rulemaking following receipt of an adverse comment, we will publish a separate notice of proposed rulemaking (NPRM) and provide a new opportunity for comment. A comment is considered “adverse” if the comment explains why this rule or a part of this rule would be inappropriate, including a challenge to its underlying premise or approach, or would be ineffective or unacceptable without a change.

## VI. Regulatory Analyses

The Coast Guard developed this direct final rule after considering numerous statutes and executive orders related to this rulemaking. Below, the Coast Guard summarizes its analyses based on these statutes or executive orders.

### A. Regulatory Planning and Review

Executive Orders 12866 (“Regulatory Planning and Review”) and 13563 (“Improving Regulation and Regulatory Review”) direct agencies to assess the 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 direct final rule has not been designated a “significant regulatory action”, under section 3(f) of Executive Order 12866. Accordingly, the direct final rule has not been reviewed by the Office of Management and Budget (OMB). A regulatory assessment of the direct final rule follows.

This direct final rule conforms Coast Guard regulations to sec. 316, which eliminated the exception of engine ratings originally found within 46 U.S.C. 8104(g)(1). Sec. 316 amended 46 U.S.C. 8104(g)(1) to allow coal passers, firemen, oilers, and water tenders serving on certain offshore support vessels, towing vessels, and barges to be divided into at least two watches. In order to align the regulations with the amended statute, this rule will revise 46 CFR 15.705(b) by deleting the words “coal passers, firemen, . . . and water tenders,” and 46 CFR 15.705(c)(1) by deleting the words “except the coal passers, firemen, oilers, and water tenders.”

### Affected Population

The changes in 46 CFR 15.705(c)(1) clarify that the sea service credit afforded to all qualified members of the engine department, on certain offshore support vessels, towing vessels and barges is consistent with revised 46 U.S.C. 8104(g)(1). The National Maritime Center of the Coast Guard identified approximately 18,721 such mariners holding valid licenses as of the end of 2014. This figure constitutes the total number of mariners that this rule could affect and includes valid licenses for Unlicensed Engine Ratings and QMED with a variety of job descriptions. Before the statute was amended, these unlicensed mariners could not be divided into two watches to work 12-hour shifts and, therefore, could not receive 1½-day sea service credit for 12 hours of work that licensed mariners both on deck and in the engine room are allowed. The changes in 46 CFR 15.705(b) align with revised 46 U.S.C. 8104(d) by removing the coal passer, fireman, and watertender exceptions to simplify the statute and regulations.

### Costs

This direct final rule will result in no adverse impacts or costs to the industry and affected mariners. On the contrary, the industry is urging speedy revision of our regulations because delaying this rule would have a negative impact on the sea service credit and career

advancement of affected mariners due to confusion caused by conflicting statutory and regulatory provisions. This rule will not result in a change to the Coast Guard’s budget and it will not increase federal spending.

### Benefits

The direct final rule aligns Coast Guard regulations with the amended statute and clarifies that affected mariners are entitled to benefits allowed by 46 CFR 10.107 and 10.232(h)(2). The primary benefit of this rule is to reduce confusion and clarify that affected mariners are allowed to receive 1½ days sea service credit for working 12-hour shifts on a two watch schedule that can be utilized for career advancement and renewal. Additionally, by making the accrual of sea service credit comparable to other mariners serving on the same vessels, vessel owners will have greater assurance of having a steady supply of mariners with higher ratings that are required to operate offshore supply vessels.

### Alternatives

The Coast Guard considered four alternatives for this direct final rule:

- Alternative 1: No action
- Alternative 2: Delayed Action
- Alternative 3: Develop Policy

The no-action alternative (Alternative 1) would cause confusion because it would leave regulations in place that contradict the new statute. Therefore, the Coast Guard rejected this alternative.

The Coast Guard rejected the delayed-action alternative (Alternative 2) for the same reason. The misalignment between 46 U.S.C. 8104 and the corresponding regulations is causing confusion among mariners, and there is no discernible advantage in delay.

The develop policy alternative (Alternative 3) could grant the affected engine ratings the same sea service credit as the officers and deck ratings aboard the affected vessels. The Coast Guard rejected this alternative, however, because policy properly provides either: guidance about accepted methods for meeting regulations; or short term solutions, within the limits of existing regulations, to provide relief until amended regulations can be promulgated.

In this case, the time and effort required by the Coast Guard to develop and publish relevant policy would equal or exceed that expected to amend the regulation with a direct final rule. In addition, after publishing the policy, the regulation would still require amendment to be consistent with the statute. Therefore, the Coast Guard rejected this alternative.

<sup>1</sup> 33 CFR 1.05–55 provides that a direct final rule effective date is “generally at least 90 days after the date of publication” and “[t]he public will usually be given at least 60 days” to submit comments.

### B. Small Entities

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Coast Guard prepared this Regulatory Flexibility Analysis (RFA) that examines the impacts of this direct final rule on small entities (5 U.S.C. 601 *et seq.*). Under the RFA, we have considered whether this rule will have a significant economic impact on a substantial number of small entities. The term of “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of fewer than 50,000.

The direct final rule will regulate mariners who are individually responsible for obtaining their appropriate sea service credit for career advancement. In addition, current and future mariners will not incur any costs to comply with this rule. Finally, individuals, such as the mariners regulated by this rule, are not small entities under the definition of a small entity in the RFA. Therefore, we certify that this direct final rule will not have a significant economic impact on a substantial number of small entities under section 605(b) of the Regulatory Flexibility Act.

The Coast Guard is interested in the potential impacts from this direct final rule on small businesses and we request public comment on these potential impacts. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rulemaking would have a significant economic impact on it, please submit a comment to the address under **ADDRESSES**. In your comment, explain why you think it qualifies and how, and to what degree this rule would economically affect it.

### C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard wants to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Mr. Davis Breyer, Maritime Personnel Qualifications Division (CG–OES–1), Coast Guard; email [Davis.J.Breyer@uscg.mil](mailto:Davis.J.Breyer@uscg.mil), telephone (202) 372–1445. 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.

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).

### D. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

### E. 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. The Coast Guard has analyzed this rule under that Order and has determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132. It is well settled that States may not regulate in categories reserved for regulation by the Coast Guard. It is also well settled that all of the categories covered in 46 U.S.C. 3306, 3703, 7101, and 8101 (design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of covered vessels), as well as the reporting of casualties and any other category in which Congress intended the Coast Guard to be the sole source of a vessel’s obligations, are within the field foreclosed from regulation by the States. (See the decision of the Supreme Court in the consolidated cases of *United States v. Locke and Intertanko v. Locke*, 529 U.S. 89, 120 S.Ct. 1135 (2000)). Since this rule involves the documentation of merchant mariners manning covered U.S. vessels, it is a matter of personnel qualifications, which is a field reserved for regulation by the Coast Guard. Because States may not promulgate rules within this category, the rule is consistent with the principles of federalism and preemption requirements in Executive Order 13132.

### F. 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, the Coast Guard does discuss the effects of this rule elsewhere in this preamble.

### G. 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.

### H. 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.

### I. Protection of Children

The Coast Guard has 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.

### J. 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.

### K. Energy Effects

The Coast Guard has analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Coast Guard has determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under E.O. 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has

not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

#### L. Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

#### M. Environment

The Coast Guard has analyzed this rule under DHS Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and has concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded under section 2.B.2, figure 2-1, paragraph (34) (a) and (c) of the Instruction. This rule involves procedural changes and the licensing of mariners under sec. 316. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

#### List of Subjects in 46 CFR Part 15

Reporting and recordkeeping requirements, Seamen, Vessels.

For the reasons discussed in the preamble, the Coast Guard amends 46 CFR part 15 as follows:

## PART 15—MANNING REQUIREMENTS

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

**Authority:** 46 U.S.C. 2101, 2103, 3306, 3703, 8101, 8102, 8104, 8105, 8301, 8304, 8502, 8503, 8701, 8702, 8901, 8902, 8903, 8904, 8905(b), 8906, 9102, and 8103; sec. 617, Pub. L. 111-281, 124 Stat. 2905; and Department of Homeland Security Delegation No. 0170.1.

#### § 15.705 Watches.

■ 2. Amend § 15.705 as follows:

- a. In paragraph (b), remove the words “, coal passers, firemen, oilers, and watertenders” and add in their place the words “, and oilers”; and
- b. In paragraph (c)(1) introductory text, remove the words “(except the coal passers, firemen, oilers, and watertenders)”.

**J.G. Lantz,**

*Director, Commercial Regulations and Standards, U.S. Coast Guard.*

[FR Doc. 2015-27062 Filed 10-23-15; 8:45 am]

**BILLING CODE 9110-04-P**

# Proposed Rules

Federal Register

Vol. 80, No. 206

Monday, October 26, 2015

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

## DEPARTMENT OF ENERGY

### 10 CFR Part 430

[Docket No. EERE-2015-BT-STD-0003]

RIN 1904-AD49

### Energy Conservation Standards for Pool Heaters

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

**ACTION:** Notice of data availability (NODA).

**SUMMARY:** The U.S. Department of Energy (DOE) has completed a preliminary analysis for purposes of considering energy conservation standards for electric pool heaters. At this time, DOE is not proposing energy conservation standards for electric pool heaters. However, it is publishing this analysis so stakeholders can review the analysis's output and the underlining assumptions and calculations that might ultimately support a proposed standard. DOE encourages stakeholders to provide any additional data or information that may improve the analysis. The analysis is now publicly available at on the DOE Web site.

**DATES:** DOE will accept comments, data, and other information regarding this rulemaking no later than December 10, 2015. See section IV, "Public Participation," of this document for details.

**ADDRESSES:** The direct heating equipment and pool heater docket (EERE-2015-BT-STD-0003) is available for review at [www.regulations.gov](http://www.regulations.gov). It includes relevant **Federal Register** notices, the Request for Information, public comments, and other relevant documents/materials. All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure. The [www.regulations.gov](http://www.regulations.gov) Web page contains instructions on how

to access all documents in the docket, including public comments.

Also, the DOE Web page for pool heaters (which includes additional information about existing standards and test procedures, and the history and impacts of previous DOE regulatory actions for these products) may be viewed at [http://www1.eere.energy.gov/buildings/appliance\\_standards/product.aspx/productid/47](http://www1.eere.energy.gov/buildings/appliance_standards/product.aspx/productid/47) and contains links to the aforementioned docket.

For detailed instructions on submitting comments and additional information on the rulemaking process, see section IV, "Public Participation," of this document. For further information on how to submit a comment or to review other public comments and the docket contact Ms. Brenda Edwards at (202) 586-2945 or by email: [Brenda.Edwards@ee.doe.gov](mailto:Brenda.Edwards@ee.doe.gov).

#### FOR FURTHER INFORMATION CONTACT:

Mr. John Cymbalsky, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 287-1692. Email: [John.Cymbalsky@ee.doe.gov](mailto:John.Cymbalsky@ee.doe.gov).

Ms. Sarah Butler, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 586-1777. Email: [Sarah.Butler@hq.doe.gov](mailto:Sarah.Butler@hq.doe.gov).

For information on how to submit or review public comments, contact Ms. Brenda Edwards, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 586-2945. Email: [Brenda.Edwards@ee.doe.gov](mailto:Brenda.Edwards@ee.doe.gov).

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#### I. Authority

Title III, Part B<sup>1</sup> of the Energy Policy and Conservation Act of 1975 ("EPCA" or "the Act"), Public Law 94-163 (codified at 42 U.S.C. 6291-6309) sets forth a variety of provisions designed to improve energy efficiency and establishes the Energy Conservation Program for Consumer Products Other Than Automobiles.<sup>2</sup> This program includes most major household appliances (collectively referred to as "covered products"), including the two covered products that are the subject of this rulemaking process: Direct heating equipment (DHE) and pool heaters.<sup>3</sup> (42 U.S.C. 6292(a)(9) and (11)) Under EPCA, this energy conservation program generally consists of four parts: (1) Testing; (2) labeling; (3) establishing Federal energy conservation standards; and (4) certification and enforcement procedures.

EPCA prescribes specific energy conservation standards for pool heaters and direct heating equipment. (42 U.S.C. 6295(e)(2), (3)) EPCA directed DOE to conduct two cycles of rulemakings to determine whether to amend its standards for direct heating equipment and pool heaters. (42 U.S.C. 6295(e)(4)) The statute further requires DOE to publish a notice of proposed rulemaking including new proposed standards or a notice of determination that the standards for a product need not be amended no later than 6 years after issuance of any final rule establishing or amending standards for that product. (42 U.S.C. 6295(m)(1)) DOE last promulgated a final rule on April 16, 2010, amending its energy conservation standards for direct heating equipment and pool heaters,

<sup>1</sup> For editorial reasons, upon codification in the U.S. Code, Part B was redesignated as Part A.

<sup>2</sup> All references to EPCA in this document refer to the statute as amended through the Energy Efficiency Improvement Act, Public Law 114-11 (April 30, 2015).

<sup>3</sup> A "pool heater" means "an appliance designed for heating nonpotable water contained at atmospheric pressure, including heating water in swimming pools, spas, hot tubs and similar application." (42 U.S.C. 6291(25)) This definition of coverage does not specify a fuel type, and so electric pool heaters are considered to be covered products under EPCA even though energy conservation standards are not currently established.



constituting the first of these two required rulemakings. 75 FR 20112. The current rulemaking satisfies the statutory requirements under EPCA to conduct a second round of review of the DHE and pool heater standards. (42 U.S.C. 6295(e)(4)(B)) Additionally, this rulemaking will satisfy the requirement for DOE to publish a notice of proposed rulemaking containing proposed standards or a notice of determination that the standards for direct heating equipment and pool heaters do not need to be amended by April 16, 2016. (42 U.S.C. 6295(m)(1)). If DOE were to publish a notice of proposed rulemaking containing proposed amendments to its standards for either direct heating equipment or pool heaters, DOE would be required to issue a final rule amending the standards no later than 2 years after issuance of the notice. (42 U.S.C. 6295(m)(3)(A))

EPCA also provides criteria for prescribing amended standards for covered products generally, including direct heating equipment and pool heaters. As indicated above, any such amended standard must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Additionally, EPCA provides specific prohibitions on prescribing such standards. DOE may not prescribe an amended standard for any of its covered products for which it has not established a test procedure. (42 U.S.C. 6295(o)(3)(A)) Further, DOE may not prescribe a standard if DOE determines by rule that such standard would not result in “significant conservation of energy,” or “is not technologically feasible or economically justified.” (42 U.S.C. 6295(o)(3)(B)) EPCA also provides that in deciding whether a standard is economically justified for covered products, DOE must, after receiving comments on the proposed standard, determine whether the benefits of the standard exceed its burdens by considering, to the greatest extent practicable, the following seven factors:

1. The economic impact of the standard on manufacturers and consumers of the products subject to the standard;
2. The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the imposition of the standard;
3. The total projected amount of energy (or, as applicable, water) savings

likely to result directly from the imposition of the standard;

4. Any lessening of the utility or the performance of the covered products likely to result from the imposition of the standard;

5. The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the imposition of the standard;

6. The need for national energy and water conservation; and

7. Other factors the Secretary of Energy (Secretary) considers relevant. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

In addition, EPCA, as amended, establishes a rebuttable presumption that any standard for covered products is economically justified if the Secretary finds that “the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy (and as applicable, water) savings during the first year that the consumer will receive as a result of the standard,” as calculated under the test procedure in place for that standard. (42 U.S.C. 6295(o)(2)(B)(iii))

EPCA also contains what is commonly known as an “anti-backsliding” provision. (42 U.S.C. 6295(o)(1)) This provision mandates that the Secretary not prescribe any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. EPCA further provides that the Secretary may not prescribe an amended standard if interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States of any product type (or class) with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary’s finding. (42 U.S.C. 6295(o)(4)) Under 42 U.S.C. 6295(q)(1), EPCA specifies requirements applicable to promulgating standards for any type or class of covered product that has two or more subcategories. Under this provision, DOE must specify a different standard level than that which applies generally to such type or class of product that has the same function or intended use, if DOE determines that the products within such group: (A) Consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other

products within such type (or class) do not have and such feature justifies a higher or lower standard than applies or will apply to the other products. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies such a different standard for a group of products, DOE must consider “such factors as the utility to the consumer of such a feature” and other factors the Secretary deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which DOE established such higher or lower level. (42 U.S.C. 6295(q)(2))

Section 310(3) of the Energy Independence and Security Act of 2007 (EISA 2007; Public Law 110–140) amended EPCA to prospectively require that energy conservation standards address standby mode and off mode energy use. Specifically, when DOE adopts new or amended standards for a covered product after July 1, 2010, the final rule must, if justified by the criteria for adoption of standards in section 325(o) of EPCA, incorporate standby mode and off mode energy use into a single standard if feasible, or otherwise adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)) On December 17, 2012 DOE promulgated a final rule amending its test procedures for vented direct heating equipment and pool heaters to incorporate standby and off-mode energy consumption. 77 FR 74559. The amendments related to standby and off-mode energy consumption were not required for purposes of compliance until the compliance date of the next standards final rule for those products. *Id.* This rulemaking, if amended standards are ultimately adopted, would serve as the next energy conservation standards rulemaking subsequent to these test procedure amendments, and therefore this rulemaking will take into account standby and off-mode energy consumption.

Finally, Federal energy conservation requirements for covered products generally supersede State laws or regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) DOE can, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of section 327(d) of the Act. (42 U.S.C. 6297(d))

Before proposing a standard, DOE typically seeks public input about the analytical framework, models, and tools that it will use to evaluate standards for the product or equipment at issue and the results of preliminary analyses DOE

performed for that product or equipment. This NODA announces the availability of the preliminary Technical Support Document (TSD), which details the preliminary analyses and summarizes the preliminary results of DOE's analyses for electric pool heaters.

## II. History of Energy Conservation Standards Rulemaking for Pool Heaters

### A. Background

Currently, energy conservation standards are established for vented home heating equipment (a form of direct heating equipment) and gas-fired pool heaters. (10 CFR 430.32(i) and (k)) DOE last amended its energy conservation standards for pool heaters and direct heating equipment through a final rule published in the **Federal Register** (FR) on April 16, 2010 (hereafter referred to as the "April 2010 final rule"). 75 FR 20112. (*codified at* 10 CFR 430.32(i) and (k)). Compliance with the amended standards was required beginning on April 16, 2013. *Id.* As described above in section I, EPCA directed DOE to conduct two cycles of rulemakings regarding standards for DHE and pool heaters, and this rulemaking satisfies the statutory requirements under EPCA to conduct a second round of review of the DHE and pool heater standards. (42 U.S.C. 6295(e)(4)(B)) To initiate this rulemaking, DOE issued a Request for Information (RFI) in the **Federal Register** on March 26, 2015 (hereafter "March 2015 RFI"). 80 FR 15922. Through this RFI, DOE requested data and information pertaining to its technical and economic analyses for direct heating equipment and pool heaters.

In addition to determining whether energy conservation standards for vented home heating equipment and gas-fired pool heaters should be amended, DOE is considering during this rulemaking whether it is appropriate to establish energy conservation standards for electric pool heaters, including both electric resistance pool and spa heaters as well as electric heat pump pool heaters. As described in section I, although energy conservation standards for electric pool heaters have not previously been set, the definition of coverage for pool heaters found at 42 U.S.C. 6291(25) does not specify a fuel type, and therefore all pool heaters (including electric) are considered covered products under EPCA. Among other topics, the March 2015 RFI sought data and information pertaining specifically to electric pool heaters, including electric resistance pool and spa heaters as well as electric

heat pump pool heaters. Since energy conservation standards have not previously been established for electric pool heaters, DOE is publishing this preliminary analysis for electric pool heaters in order to solicit feedback regarding the methodologies used and results obtained based on information collected during the March 2015 RFI public comment period and preliminary confidential manufacturer interviews, among other sources. DOE does not plan to publish a similar preliminary analysis for vented home heating equipment and gas-fired pool heaters. DHE product offerings have not markedly changed since the final rule analysis in 2010 (with the exception of condensing technology for fan-type wall furnaces). Additionally, DOE has performed testing on vented home heating equipment (a subset of DHE) and through this process has built sufficient knowledge, in combination with the previous rulemaking analyses and the March 2015 RFI, to forgo a preliminary analysis for these products. DOE requests comment on its determination to forgo a preliminary analysis for these products and notes that interested parties will have the opportunity to comment on DOE's analyses for vented home heating equipment and gas-fired pool heaters during the Notice of Proposed Rulemaking (NOPR) phase of the rulemaking process.

DOE completed a separate test procedure rulemaking for direct heating equipment and pool heaters by publishing in the **Federal Register** a final rule on January 6, 2015. 80 FR 792. (*Codified at* 10 CFR part 430, subpart B, Appendix P) Any energy conservation standards for pool heaters of any fuel type adopted as part of this rulemaking would be based on the updated test procedure.

### B. Current Rulemaking Process

As indicated above, in initiating this rulemaking DOE published a Request for Information on March 26, 2015. Among other topics, DOE solicited data and information pertaining to electric resistance and electric heat pump pool and spa heaters. Comments received since publication of the March 2015 RFI have helped DOE identify issues and collect data related to the preliminary analyses for electric pool heaters. Chapter 2 of the preliminary TSD summarizes and addresses the comments received in response to the March 2015 RFI.

## III. Summary of the Analyses Performed by DOE

For the electric pool heaters covered in this rulemaking, DOE conducted in-

depth technical analyses in the following areas: (1) Engineering; (2) markups to determine product price; (3) energy use; (4) life-cycle cost and payback period; and (5) national impacts. The preliminary TSD that presents the methodology and results of each of these analyses is available at [http://www1.eere.energy.gov/buildings/appliance\\_standards/rulemaking.aspx?ruleid=113](http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx?ruleid=113).

DOE also conducted, and has included in the preliminary TSD, several other analyses that support the major analyses or are preliminary analyses that will be expanded upon for a NOPR if DOE determines that amended energy conservation standards are technologically feasible, economically justified, and would save a significant amount of energy, based on the information available to DOE. These analyses include: (1) The market and technology assessment; (2) the screening analysis, which contributes to the engineering analysis; and (3) the shipments analysis, which contributes to the life-cycle cost (LCC) and payback period (PBP) analysis and national impact analysis (NIA). In addition to these analyses, DOE has begun preliminary work on the manufacturer impact analysis and has identified the methods to be used for the LCC consumer subgroup analysis, the emissions analysis, the employment impact analysis, the regulatory impact analysis, and the utility impact analysis. DOE will expand on these analyses in the NOPR.

### A. Market and Technology Assessment

When initiating an analysis of potential energy efficiency standards for a residential product, DOE develops information for the products and characterizes the market and industry structure, evaluating both current and historical information. This activity is primarily based on a review of publicly-available information.

When evaluating and establishing energy conservation standards, DOE generally divides covered products into product classes by the type of energy used or by capacity or other performance-related features that affect efficiency. DOE has tentatively decided to differentiate between electric pool heaters and electric spa heaters on the basis that each of these two products have different characteristics which have the potential of affecting efficiency. Specifically, electric spa heaters often have space constraints which would impede the use of higher efficiency technologies. DOE therefore considered two product classes—electric pool heaters and electric spa

heaters—for this preliminary analysis. DOE recognizes that electric spa heaters, being integral to the construction of a spa or hot tub, use electric resistance heating elements due to space constraints and DOE has tentatively determined that heat pump technology is therefore not a viable option for electric spa heaters. DOE did not analyze electric spa heaters because it did not identify technologies that would measurably increase the integrated thermal efficiency of these products. DOE does, however, consider electric resistance to be a baseline technology for the electric pool heater product class, since electric resistance heaters are available at capacities that could serve a pool and electric heat pumps represent an improvement in efficiency over these products.

Energy conservation standards may be proposed later in the rulemaking for either, both, or neither of these potential product classes in addition to gas-fired pool heaters. (42 U.S.C. 6295(q)) Alternatively, DOE could propose different product classes than those analyzed in its preliminary analysis if comments, information, or additional analysis be provided that suggest doing so would be more appropriate for the pool and spa heater market. Chapter 3 of the preliminary TSD addresses the market and technology assessment.

#### *B. Engineering Analysis*

The engineering analysis establishes the relationship between the manufacturer selling price and efficiency levels of the products that DOE is evaluating as potential energy conservation standards. This relationship serves as the basis for cost-benefit calculations for individual consumers, manufacturers, and the Nation. The engineering analysis identifies representative baseline products, which is the starting point for analyzing technologies that provide energy efficiency improvements. “Baseline” refers to a model or models having features and technologies typically found in minimally-efficient products currently available on the market and, for products already subject to energy conservation standards, a model that just meets the current standard. After identifying the baseline models, DOE estimated manufacturer selling prices by using a consistent methodology and pricing scheme that includes material costs and manufacturer markups. DOE used these inputs to develop manufacturer selling prices for the baseline and more-efficient designs. Later, in the markups analysis to determine the installed price, DOE converts these manufacturer

selling prices into installed prices. Chapter 5 of the preliminary TSD discusses the engineering analysis.

#### *C. Markups To Determine Commercial Consumer Prices*

DOE derives consumer installed prices based on manufacturer markups, retailer markups, distributor markups, contractor markups (where appropriate), and sales taxes. In deriving these markups, DOE determines the major distribution channels for product sales, the markup associated with each party in each distribution channel, and the existence and magnitude of differences between markups for baseline products (baseline markups) and higher-efficiency products (incremental markups). DOE calculates both overall baseline and overall incremental markups based on the product markups at each step in each distribution channel. Chapter 6 of the preliminary TSD addresses the markups analysis.

#### *D. Energy Use Analysis*

The energy use analysis provides estimates of the annual energy consumption of electric pool heaters. The energy use analysis seeks to estimate the range of energy consumption of products that meet each of the efficiency levels considered in a given rulemaking as they are used in the field. DOE uses these values in the LCC and PBP analyses and in the NIA. Chapter 7 of the preliminary TSD addresses the energy use analysis.

#### *E. Life-Cycle Cost and Payback Period Analyses*

The LCC and PBP analyses determine the economic impact of potential standards on individual consumers. The LCC is the total cost to the consumer of purchasing, installing, and operating the considered pool heater over the course of its lifetime. The LCC analysis compares the LCCs of products designed to meet possible energy conservation standards with the LCC of the products likely to be installed in the absence of standards. DOE determines LCCs by considering: (1) Total installed cost to the purchaser (which consists of manufacturer selling price, distribution chain markups, sales taxes, and installation cost); (2) the operating cost of the product (energy cost and maintenance and repair cost); (3) product lifetime; and (4) a discount rate that reflects the real consumer cost of capital and puts the LCC in present-value terms. The PBP represents the number of years needed to recover the increase in purchase price (including installation cost) of higher-efficiency products through savings in the

operating cost of the products. PBP is calculated by dividing the incremental increase in installed cost of the higher-efficiency products, compared to the baseline products, by the annual savings in operating costs. Chapter 8 of the preliminary TSD addresses the LCC and PBP analyses.

#### *F. National Impact Analysis*

The NIA estimates the national energy savings (NES) and the net present value (NPV) of total consumer costs and savings expected to result from amended standards at specific efficiency levels (referred to as candidate standard levels). DOE calculated NES and NPV for each candidate standard level for electric pool heaters as the difference between a base-case forecast (without amended standards) and the standards-case forecast (with standards). DOE determined national annual energy consumption by multiplying the number of units in use (by vintage) by the average unit energy consumption (also by vintage). Cumulative energy savings are the sum of the annual NES determined for the lifetime of the products shipped from 2022–2051. This 30-year analysis period begins in 2022, the expected first full year of compliance with the amended standards. The NPV is the sum over time of the discounted net savings each year, which consists of the difference between total operating cost savings and increases in total installed costs. Critical inputs to this analysis include shipments projections, estimated product lifetimes, product installed costs and operating costs, product annual energy consumption, the base case efficiency projection, and discount rates. Chapter 10 of the preliminary TSD addresses the NIA.

### **IV. Public Participation**

DOE invites input from the public on all the topics described above. The preliminary analytical results are subject to revision following further review and input from the public. A complete TSD is available for this analysis, and the Executive Summary of the TSD identifies specific issues on which DOE seeks comment. The final rule establishing any amended energy conservation standards will contain the final analytical results and will be accompanied by a final rule TSD.

The TSD is available at: [http://www1.eere.energy.gov/buildings/appliance\\_standards/rulemaking.aspx?ruleid=113](http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx?ruleid=113). DOE is also interested in receiving views concerning other relevant issues that participants believe would affect energy conservation standards for this

equipment or that DOE should address in the NOPR.

DOE welcomes all interested parties to submit in writing by December 10, 2015 comments, data, and other information on matters addressed in the TSD and on other matters relevant to consideration of energy conservation standards for pool heaters.

After the closing of the comment period, DOE will consider all timely-submitted comments and additional information obtained from interested parties, as well as information obtained through further analyses. Afterward, DOE will publish either a determination that standards for electric pool heaters need not be established or a NOPR proposing to establish those standards. The NOPR would include proposed energy conservation standards for the products covered by the rulemaking, and members of the public would be given an opportunity to submit written and oral comments on the proposed standards.

#### A. Submission of Comments

DOE will accept comments, data, and other information regarding this rulemaking no later than the date provided at the beginning of this document. Please submit comments, data, and other information as provided in the **ADDRESSES** section. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format and avoid the use of special characters or any form of encryption. Comments in electronic format should be identified by the Docket Number EERE-2015-BT-STD-0003 and/or RIN 1904-AD49 and, wherever possible, carry the electronic signature of the author. No telefacsimiles (faxes) will be accepted.

Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit two copies: One copy of the document including all the information believed to be confidential and one copy of the document with the information believed to be confidential deleted. DOE will make its own determination as to the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made

available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) a date upon which such information might lose its confidential nature due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

#### V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of data availability of the preliminary technical support document.

Issued in Washington, DC, on October 15, 2015.

**Kathleen B. Hogan,**

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

[FR Doc. 2015-27203 Filed 10-23-15; 8:45 am]

**BILLING CODE 6450-01-P**

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Chapter II

[Docket No. CPSC-2015-0030]

#### Notice of Availability: CPSC Plan for Retrospective Review of Existing Rules

**AGENCY:** U.S. Consumer Product Safety Commission.

**ACTION:** Notice of availability.

**SUMMARY:** The Consumer Product Safety Commission (“Commission,” or “CPSC”) has approved a document titled, “Plan for Retrospective Review of Existing Rules.” CPSC seeks comments on this plan.

**DATES:** Submit comments by December 28, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CPSC-2015-0030, by any of the following methods:

*Electronic Submissions:* Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through [www.regulations.gov](http://www.regulations.gov). The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

*Written Submissions:* Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission,

Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

*Instructions:* All submissions received must include the agency name and docket number for this document. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

*Docket:* For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number CPSC-2015-0030, into the “Search” box, and follow the prompts.

#### FOR FURTHER INFORMATION CONTACT:

Patricia K. Adair, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850-3213; telephone: (301) 987-2238; email: [padair@cpsc.gov](mailto:padair@cpsc.gov).

**SUPPLEMENTARY INFORMATION:** The Commission has approved a Plan for Retrospective Review of Existing Rules (“Plan”) that sets forth a method for identifying and reconsidering certain rules that are obsolete, unnecessary, unjustified, excessively burdensome, counterproductive, or ineffective, or that otherwise would benefit from modification. The Plan’s review processes are intended to facilitate the identification of rules that warrant repeal or modification, including those that could benefit from strengthening, complementing, or modernizing. The Plan is consistent with Executive Orders 13579,<sup>1</sup> 13563<sup>2</sup> and 13610.<sup>3</sup> The Plan is available on the Commission’s Web site at: <http://www.cpsc.gov/Global/Regulations-Laws-and-Standards/Rulemaking/DraftRuleReviewPlanSeptember2015Final.pdf>. Please submit comments as directed in the **ADDRESSES** section of this document.

<sup>1</sup> 76 FR 41587 (July 11, 2011). The President. Executive Order 13579 of July 11, 2011. Regulation and Independent Regulatory Agencies.

<sup>2</sup> 76 FR 3821 (January 18, 2011). The President. Executive Order 13563 of January 18, 2011. Improving Regulation and Regulatory Review.

<sup>3</sup> 77 FR 28469 (May 10, 2012). The President. Executive Order 13610 of May 10, 2012. Identifying and Reducing Regulatory Burdens.

Dated: October 15, 2015.

**Todd A. Stevenson,**  
Secretary, Consumer Product Safety  
Commission.

[FR Doc. 2015-26695 Filed 10-23-15; 8:45 am]

BILLING CODE 6355-01-P

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Ch. II

[Docket No. CPSC-2015-0022]

#### Petition Requesting Rulemaking on Products Containing Organohalogen Flame Retardants; Notice of Extension of Comment Period; Notice of Opportunity for Oral Presentation of Comments

**AGENCY:** U.S. Consumer Product Safety  
Commission.

**ACTION:** Extension of comment period  
and notice of opportunity for oral  
presentation of comments.

**SUMMARY:** The United States Consumer  
Product Safety Commission  
("Commission" or "CPSC") on August  
19, 2015 published a notice that the  
Commission received a petition for  
rulemaking under the Federal  
Hazardous Substances Act ("FHSA")  
regarding additive organohalogen flame  
retardants. The notice invited the public  
to submit written comments concerning  
the petition by October 19, 2015. The  
Commission has received two requests  
to extend the comment period. In  
response to these requests, the  
Commission is extending the comment  
period to January 19, 2016.  
Additionally, the Commission  
announces that there will be an  
opportunity for interested persons to  
present oral comments on the petition.

**DATES:** The comment period for the  
proposed rule published August 19,  
2015 (80 FR 50238), is extended. Submit  
comments by January 19, 2016. The  
meeting for interested persons to  
present oral comments on the petition  
will begin at 10 a.m., December 9, 2015,  
at 4330 East-West Highway, Bethesda,  
MD 20814. Requests to make oral  
presentations and the written text of any  
oral presentations must be received by  
the Office of the Secretary not later than  
5 p.m. Eastern Standard Time (EST) on  
December 2, 2015.

**ADDRESSES:** You may submit comments,  
identified by Docket No. CPSC-2015-  
0022, by any of the following methods:

*Electronic Submissions:* Submit  
electronic comments to the Federal  
eRulemaking Portal at: <http://www.regulations.gov>. Follow the  
instructions for submitting comments.

The Commission does not accept  
comments submitted by electronic mail  
(email), except through  
[www.regulations.gov](http://www.regulations.gov). The Commission  
encourages you to submit electronic  
comments by using the Federal  
eRulemaking Portal, as described above.

*Written Submissions:* Submit written  
submissions by mail/hand delivery/  
courier to: Office of the Secretary,  
Consumer Product Safety Commission,  
Room 820, 4330 East-West Highway,  
Bethesda, MD 20814; telephone (301)  
504-7923.

*Instructions:* All submissions received  
must include the agency name and  
docket number for this proposed  
rulemaking. All comments received may  
be posted without change, including  
any personal identifiers, contact  
information, or other personal  
information provided, to: <http://www.regulations.gov>. Do not submit  
confidential business information, trade  
secret information, or other sensitive or  
protected information that you do not  
want to be available to the public. If  
furnished at all, such information  
should be submitted in writing.

*Docket:* For access to the docket to  
read background documents or  
comments received, go to: <http://www.regulations.gov>, and insert the  
docket number, CPSC-2015-0022, into  
the "Search" box, and follow the  
prompts. A copy of the petition is  
available at <http://www.regulations.gov>  
under Docket No. CPSC-2015-0022,  
Supporting and Related Materials.

**FOR FURTHER INFORMATION CONTACT:** For  
information about the procedure to  
make an oral presentation, contact  
Rockelle Hammond, Office of the  
Secretary, Consumer Product Safety  
Commission, 4330 East-West Highway,  
Bethesda, MD 20814; telephone (301)  
504-7923.

#### SUPPLEMENTARY INFORMATION:

##### A. Background

On July 1, 2015, the Commission  
received a petition requesting that the  
Commission initiate rulemaking under  
the FHSA to declare several categories  
of products containing additive  
organohalogen flame retardants to be  
"banned hazardous substances." The  
petition was filed by Earthjustice and  
the Consumer Federation of America,  
which are joined by American Academy  
of Pediatrics, American Medical  
Women's Association, Consumers  
Union, Green Science Policy Institute,  
International Association of Fire  
Fighters, Kids in Danger, Philip  
Landrigan, M.D., M.P.H., League of  
United Latin American Citizens,  
Learning Disabilities Association of  
America, and Worksafe.

##### B. Extension of Comment Period

On August 19, 2015, the Commission  
issued a notice that the Commission  
received the petition, and in the  
document, invited submission of  
written comments concerning the  
petition. 80 FR 50238. The Commission  
has received two requests to extend the  
comment period 90 days, due to the  
breadth and complexity of issues raised  
in the petition. The Commission has  
considered the requests and is  
extending the comment period until  
January 19, 2016.

##### C. Opportunity for Oral Presentation of Comments

The Commission is providing a forum  
for oral presentations concerning the  
petition regarding additive  
organohalogen flame retardants. See the  
information under the headings **DATES**  
and **ADDRESSES** at the beginning of this  
document for information on making  
requests to give oral presentations at the  
meeting.

Participants should limit their  
presentations to approximately 10  
minutes, exclusive of any periods of  
questioning by the Commissioners or  
CPSC staff. To prevent duplicative  
presentations, groups will be directed to  
designate a spokesperson. The  
Commission reserves the right to limit  
the time further for any presentation  
and impose restrictions to avoid  
excessive duplication of presentations.

Dated: October 15, 2015.

**Todd A. Stevenson,**  
Secretary, U.S. Consumer Product Safety  
Commission.

[FR Doc. 2015-26694 Filed 10-23-15; 8:45 am]

BILLING CODE 6355-01-P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 25

[IB Docket No. 06-123; DA 15-1147]

#### Supplemental Comments Sought on Proposed 17/24 GHz Reverse Band BSS Ground Path Operations

**AGENCY:** Federal Communications  
Commission.

**ACTION:** Proposed rule.

**SUMMARY:** In this document, the  
International Bureau of the Commission  
invites interested parties to provide any  
supplemental information or comments  
concerning the Commission's proposed  
ground-path interference rules for 17/24  
GHz Reverse Band Broadcasting-  
Satellite Service (BSS) operations.

This request is intended to refresh the record in this proceeding, and to provide parties with the opportunity to update or add to their comments, as well as allowing parties who have not filed comments in this proceeding previously to do so.

**DATES:** Submit comments on or before November 25, 2015, and replies on or before December 10, 2015.

**ADDRESSES:** You may submit comments, identified by IB Docket No. 06–123, by any of the following methods:

- *Federal Communications Commission's Web site:* <http://apps.fcc.gov/ecfs/>. Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: [FCC504@fcc.gov](mailto:FCC504@fcc.gov) or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Public Notice in IB Docket No. 06–123, DA 15–1147, adopted October 7, 2015, and released October 7, 2015. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW., Washington, DC 20554. The document also is available for download over the Internet at [http://transition.fcc.gov/Daily\\_Releases/Daily\\_Business/2015/db1007/DA-15-1147A1.pdf](http://transition.fcc.gov/Daily_Releases/Daily_Business/2015/db1007/DA-15-1147A1.pdf).

### Synopsis

On May 2, 2007, the Commission proposed rules in a Further Notice of Proposed Rulemaking (FNPRM) to mitigate ground path interference. The ground path interference issues in this proceeding have been considered and discussed among the interested parties previously. Since considerable time has passed, however, since the release of the FNPRM, the Commission asks the public to provide any updates for the record and any additional comments on the proposed rules for ground path interference mitigation in 17/24 GHz reverse-band BSS operations presented in the FNPRM.

**FOR FURTHER INFORMATION CONTACT:** Stephen Duall or Sean O'More, International Bureau, FCC, (202) 418–2453 or via the email to: [Stephen.Duall@fcc.gov](mailto:Stephen.Duall@fcc.gov) and [Sean.O'More@fcc.gov](mailto:Sean.O'More@fcc.gov).

### Comment Filing Procedures

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). See *Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: <http://apps.fcc.gov/ecfs/>.

- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington DC 20554.

*People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

### Paperwork Reduction Act

This document does not contain proposed information collection requirements required by the Paperwork Reduction Act of 1995, Public Law 104–13. It also does not impose information collection burdens for small business

concerns with fewer than 25 employees pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

Federal Communications Commission.

**Sarah Van Valzah,**

*Assistant Bureau Chief for Management, International Bureau.*

[FR Doc. 2015–27154 Filed 10–23–15; 8:45 am]

**BILLING CODE 6712–01–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Parts 223 and 224

[Docket No. 150901797–5914–01]

RIN 0648–XE163

#### Endangered and Threatened Wildlife; 90-Day Finding on a Petition To List the Thorny Skate as Threatened or Endangered Under the Endangered Species Act

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

**ACTION:** 90-day petition finding, request for information.

**SUMMARY:** We, NMFS, announce a 90-day finding on a petition to list a “Northwest Atlantic Distinct Population Segment” (DPS) or “United States DPS” of thorny skate (*Amblyraja radiata*) as threatened or endangered under the Endangered Species Act (ESA). We find that the petition to list thorny skate presents substantial scientific or commercial information indicating that the petitioned action may be warranted. We will conduct a review of the status of the species to determine if the petitioned action is warranted. To ensure that the status review is comprehensive, we are soliciting scientific and commercial information pertaining to this species from any interested party.

**DATES:** Information and comments on the subject action must be received by December 28, 2015.

**ADDRESSES:** You may submit comments, information, or data on this document, identified by NOAA–NMFS–2015–0120, by either any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to [www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0120](http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0120). Click the “Comment Now” icon, complete the

required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Julie Crocker, NMFS Greater Atlantic Regional Fisheries Office, Protected Resources Division, 55 Great Republic Drive, Gloucester, MA 01930, USA.

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

Copies of the petition and related materials are available on our Web site at: <http://www.fisheries.noaa.gov/pr/species/fish/thorny-skate.html>.

**FOR FURTHER INFORMATION CONTACT:** Julie Crocker, Protected Resources Division, 978–281–9328, or Marta Nammack, NMFS–HQ, Protected Resources Office, (301) 427–8469.

#### SUPPLEMENTARY INFORMATION:

##### Background

On May 28, 2015, we received a petition from Defenders of Wildlife and Animal Welfare Institute to list a “Northwest Atlantic DPS” of thorny skate as threatened or endangered under the ESA, or, as an alternative, to list a “United States DPS” as threatened or endangered. The petition also requests that we designate critical habitat for thorny skate. Copies of the petition are available from us (see **ADDRESSES**, above) and can be found at: <http://www.fisheries.noaa.gov/pr/species/fish/thorny-skate.html>.

##### ESA Statutory, Regulatory, and Policy Provisions and Evaluation Framework

Section 4(b)(3)(A) of the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires, to the maximum extent practicable, that within 90 days of receipt of a petition to list a species as threatened or endangered, the Secretary of Commerce make a finding on whether that petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted, and to promptly publish such finding in the **Federal Register** (16 U.S.C. 1533(b)(3)(A)). When we find that substantial scientific or commercial information in a petition

indicates the petitioned action may be warranted (a “positive 90-day finding”), we are required to promptly commence a review of the status of the species concerned, during which we will conduct a comprehensive review of the best available scientific and commercial information. In such cases, within 12 months of receipt of the petition, we must conclude the review with a finding as to whether, in fact, the petitioned action is warranted. Because the finding at the 12-month stage is based on a more thorough review of the available information, as compared to the narrow scope of review at the 90-day stage, a “may be warranted” finding does not prejudge the outcome of the status review.

Under the ESA, a listing determination may address a species, which is defined to also include subspecies and, for any vertebrate species, any DPS that interbreeds when mature (16 U.S.C. 1532(16)). A joint NMFS-U.S. Fish and Wildlife Service (USFWS) (jointly, “the Services”) policy clarifies the agencies’ interpretation of the phrase “distinct population segment” for the purposes of listing, delisting, and reclassifying a species under the ESA (61 FR 4722; February 7, 1996). A species, subspecies, or DPS is “endangered” if it is in danger of extinction throughout all or a significant portion of its range, and “threatened” if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range (ESA sections 3(6) and 3(20), respectively, 16 U.S.C. 1532(6) and (20)). Pursuant to the ESA and our implementing regulations, we determine whether species are threatened or endangered based on any one or a combination of the following five section 4(a)(1) factors: the present or threatened destruction, modification, or curtailment of habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; inadequacy of existing regulatory mechanisms; and any other natural or manmade factors affecting the species’ existence (16 U.S.C. 1533(a)(1), 50 CFR 424.11(c)).

ESA-implementing regulations issued jointly by NMFS and USFWS (50 CFR 424.14(b)) define “substantial information” in the context of reviewing a petition to list, delist, or reclassify a species as the amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted. In evaluating whether substantial information is contained in a petition, the Secretary must consider whether the petition: (1) Clearly indicates the administrative

measure recommended and gives the scientific and any common name of the species involved; (2) contains detailed narrative justification for the recommended measure, describing, based on available information, past and present numbers and distribution of the species involved and any threats faced by the species; (3) provides information regarding the status of the species over all or a significant portion of its range; and (4) is accompanied by the appropriate supporting documentation in the form of bibliographic references, reprints of pertinent publications, copies of reports or letters from authorities, and maps (50 CFR 424.14(b)(2)).

At the 90-day finding stage, we evaluate the petitioners’ request based upon the information in the petition including its references and the information readily available in our files. We do not conduct additional research, and we do not solicit information from parties outside the agency to help us in evaluating the petition. We will accept the petitioners’ sources and characterizations of the information presented if they appear to be based on accepted scientific principles, unless we have specific information in our files that indicates the petition’s information is incorrect, unreliable, obsolete, or otherwise irrelevant to the requested action. Information that is susceptible to more than one interpretation or that is contradicted by other available information will not be dismissed at the 90-day finding stage, so long as it is reliable and a reasonable person would conclude it supports the petitioners’ assertions. In other words, conclusive information indicating the species may meet the ESA’s requirements for listing is not required to make a positive 90-day finding. We will not conclude that a lack of specific information alone negates a positive 90-day finding if a reasonable person would conclude that the unknown information itself suggests an extinction risk of concern for the species at issue.

To make a 90-day finding on a petition to list a species, we evaluate whether the petition presents substantial scientific or commercial information indicating the subject species may be either threatened or endangered, as defined by the ESA. First, we evaluate whether the information presented in the petition, along with the information readily available in our files, indicates that the petitioned entity constitutes a “species” eligible for listing under the ESA. Next, we evaluate whether the information indicates that the species faces an



extinction risk that is cause for concern; this may be indicated in information expressly discussing the species' status and trends, or in information describing impacts and threats to the species. We evaluate any information on specific demographic factors pertinent to evaluating extinction risk for the species (e.g., population abundance and trends, productivity, spatial structure, age structure, sex ratio, diversity, current and historical range, habitat integrity or fragmentation), and the potential contribution of identified demographic risks to extinction risk for the species. We then evaluate the potential links between these demographic risks and the causative impacts and threats identified in section 4(a)(1).

Information presented on impacts or threats should be specific to the species and should reasonably suggest that one or more of these factors may be operative threats that act or have acted on the species to the point that it may warrant protection under the ESA. Broad statements about generalized threats to the species, or identification of factors that could negatively impact a species, do not constitute substantial information indicating that listing may be warranted. We look for information indicating that not only is the particular species exposed to a factor, but that the species may be responding in a negative fashion; then we assess the potential significance of that negative response.

Many petitions identify risk classifications made by nongovernmental organizations, such as the International Union on the Conservation of Nature (IUCN), the American Fisheries Society, or NatureServe, as evidence of extinction risk for a species. Risk classifications by other organizations or made under other Federal or state statutes may be informative, but such classification alone may not provide the rationale for a positive 90-day finding under the ESA. For example, as explained by NatureServe, their assessments of a species' conservation status do "not constitute a recommendation by NatureServe for listing under the U.S. Endangered Species Act" because NatureServe assessments "have different criteria, evidence requirements, purposes and taxonomic coverage than government lists of endangered and threatened species, and therefore these two types of lists should not be expected to coincide" (<http://www.natureserve.org/prodServices/pdf/NatureServeStatusAssessmentsListing-Dec%202008.pdf>). Additionally, species classifications under IUCN and the ESA are not equivalent, and data standards, criteria used to evaluate species and

treatment of uncertainty are also not necessarily the same. Thus, when a petition cites such classifications, we will evaluate the source of information that the classification is based upon in light of the standards on extinction risk and impacts or threats discussed above.

#### **Distribution and Life History of Thorny Skate**

The thorny skate occurs on both sides of the Atlantic. In the western North Atlantic, it ranges from western Greenland to South Carolina, and in the eastern North Atlantic, it ranges from Iceland to the southwestern coasts of Ireland and England (Bigelow and Schroeder, 1953). This species is characterized by a row of 11 to 19 large thorns running down the midline of the back and tail (Bigelow and Schroeder, 1953; Collette and Klein-MacPhee, 2002). Thorny skate are generally brown dorsally with a white ventral surface. They may reach lengths of over 39 inches (991 mm), but maximum size varies over its range.

According to Collette and Klein-MacPhee (2002), females deposit a single fertilized egg capsule, which ranges in size from 2 to 4 inches (48 to 96 mm) in length and 1.33 to 3 inches (34 to 77 mm) in width. While females with fully formed egg capsules are captured year round, the percentage of mature females with capsules is highest during the summer (Collette and Klein-MacPhee, 2002). Thorny skate feed on benthic invertebrates and fish. Thorny skates are found over a wide variety of substrates including sand, broken shell, gravel, pebbles, and soft mud and are primarily found from 20 to 3,900 feet (18 to 1200 m) deep (Collette and Klein-MacPhee, 2002). They appear to make seasonal migrations that have been noted on the Scotian Shelf and the Grand Banks, but specific details on the spatial patterns and timing are lacking (NEFSC, 2003). Kulka and Miri (2003) report a change in the spring and fall distributions resulting in a higher density and greater proportion of biomass being found in deeper waters during the spring. These aggregations, they note, appear to be correlated with warmer relative temperatures.

Sulikowski *et al.* (2005) aged thorny skate in the Gulf of Maine and estimated the oldest age to be 16 years for both males and females. For females, 50 percent maturity occurred at approximately 11 years and 875 mm (34.5 inches) total length (TL); while for males, approximately 10.9 years and 865 mm (34 inches) TL (Sulikowski *et al.*, 2006).

#### **Analysis of Petition and Information Readily Available in Our Files**

We have determined, based on the information provided in the petition and readily available in our files, that substantial information is presented in the petition indicating that the petitioned action may be warranted. The petition contains a recommended administrative measure, provides the scientific and common name, contains a detailed narrative justification for the recommended measure, provides information on the status of the species, and includes supporting documentation. Below is a synopsis of our analysis of the information provided in the petition and readily available in our files to determine whether a reasonable person would conclude that an endangered or threatened listing may be warranted as a result of any of the factors listed under section 4(a)(1) of the ESA.

#### *Population Trends*

The petitioners state that the IUCN lists the U.S. population of thorny skates as "Critically Endangered" and the Canadian population as "Vulnerable" throughout its range in the Northwest Atlantic Ocean. They conclude that the IUCN categorization proves that reasonable people have determined that the best available scientific evidence shows that the species is likely to be endangered or threatened as those terms are defined in the ESA. They state that the IUCN classification of the U.S. population of thorny skates as "Critically Endangered" means that the species is as close to extinction in the wild as possible. However, species classifications by the IUCN and under the ESA are not equivalent. We will evaluate the information that the IUCN classification is based upon in light of the ESA's standards on extinction risk and impacts or threats discussed previously.

The IUCN reviewed the status of thorny skate in 2004 and concluded that the extent of decline warranted an assessment of vulnerable globally, but critically endangered in U.S. waters. They noted that the species was relatively stable in recent years in Canada and the Northeast Atlantic yet declining in the United States. The species was assessed as "Least Concern" in the Northeast Atlantic. They also noted that the overall abundance (whether divided among subpopulations or not) still constitutes several hundred million individuals. The minimum biomass for the Northwest Atlantic was estimated at 100,000 tons, which has



been stable or increasing slightly over the last 15 years. The reasons cited for the IUCN's critically endangered classification for U.S. waters include low relative abundance (below the fisheries limit reference point), the long-term population decline, lack of population increase despite strict management laws, and the inability to monitor species-specific landings.

The petitioners cite the 2008 Skate Stock Assessment and Fishery Evaluation (SAFE) Report prepared by the Northeast Fisheries Science Center (NEFSC) as demonstrating a precipitous decline in thorny skate abundance and biomass in United States waters since the late 1970s. Skate biomass has been monitored annually by the NEFSC bottom trawl survey since 1963. The survey occurs from Cape Lookout to the Scotian Shelf. Currently, this survey is the only long-term, comprehensive source of information on the relative abundance of thorny skates in U.S. waters, which are primarily distributed in the Gulf of Maine. Based on this information, the survey biomass index of thorny skates has steadily declined from a high 3-year average of 6.17 kg/tow in 1969 to 1971, to a low of 0.12 kg/tow in 2011 to 2013. The petition notes that when the Northeast skate complex Fishery Management Plan (FMP) was implemented by us in 2003, thorny skate was determined to be "overfished" because the biomass index that year (0.74 kg/tow) was below the established biomass threshold (2.2 kg/tow) and below the biomass target (4.41 kg/tow). The petitioners correctly note that the current biomass threshold and biomass target are 2.06 and 4.13 kg/tow, respectively. The petitioners correctly state that the most recent 3-year average mean biomass survey from 2011–2013 (0.12 kg/tow) is the lowest in the time series and that we have determined that overfishing is occurring. A stock that is subject to overfishing has a harvest rate higher than the rate that produces its "maximum sustainable yield" (MSY). MSY is the largest long-term average catch that can be taken from a stock under prevailing environmental and fishery conditions. A stock that is overfished has a population size that is too low and would jeopardize the stock's ability to produce its MSY. "Overfished" can be the result of many factors, including, but not limited to, overfishing.

The petitioners further state that Canadian indices of thorny skate have also demonstrated a precipitous decline over the past four decades. They reference a report by Canada's Committee on the Status of Endangered Wildlife in Canada (COSEWIC 2012)

noting that thorny skate dominates Canadian catches of skate species, composing approximately 90 percent of rajids caught in survey trawls (COSEWIC 2012). In 2012, COSEWIC, which was established as a legal entity under Canada's Species at Risk Act, published an assessment of the status of thorny skate in Canada and classified thorny skate as a "species of special concern;" COSEWIC assessments are considered advice to the Government of Canada on the status of wildlife species, but it is up to the Governor in Council (a subcommittee of federal cabinet ministers), on the recommendation of the Minister of the Environment, to decide whether such species should be added to the List of Wildlife Species at Risk. A COSEWIC assessment of "species of special concern" means that thorny skate may become "a threatened or an endangered species because of a combination of biological characteristics and identified threats." COSEWIC made this designation because the species has undergone severe population declines over the southern part of its distribution in Canada (specifically, the Scotian Shelf/Bay of Fundy and Georges Bank areas), its range has contracted, and declines have continued in spite of a reduction in fishing mortality. However, the report also notes that the abundance of mature individuals in the northern part of its range has been increasing and is approaching 1970s abundance levels. The report indicates that on the Scotian Shelf and Bay of Fundy, the abundance of immature skates has declined over 76 percent from 1970 to 2010 and that the rate of decline for mature skates was 95 percent over the same period. The authors note that there is no evidence that these declines are due to individuals moving north. The report also indicates that the abundance of juvenile thorny skates on Georges Bank declined by 40 percent from 1987–2008, and the abundance of adults declined by 85 percent over the same period. In the southern Gulf of St. Lawrence, abundance of thorny skate of all sizes has fluctuated between 1971 and 2010 and was lower at the end of the time series. The report notes that adults declined by 95 percent from 1971–2010 and that this matches increases in natural mortality over this period (citing Benoit and Swan 2011). The rate of decline for juveniles over this period was 32 percent, although there was an increase from 2003–2010. They note the uncertainty with how an apparently large number of juveniles could be produced by so few adults. Abundance trends could not be calculated for the Baffin Bay/Davis Strait/Ungava Bay

region. Based on limited data, the report concludes that thorny skate abundance in the Grand Banks to Labrador Shelf area has fluctuated without trend between 1978 and 2010. On the southern Labrador Shelf, thorny skate declined until 1995 and then stabilized or increased thereafter. For example, adults declined by 91 percent from 1997 to 1994 but subsequently increased by 821 percent from 1995 to 2008. Similar patterns of decline and then increased abundance are reported for the Grand Banks.

The petitioners state that since the mid-1980s, the range of the thorny skate on the Grand Banks has been contracting (Kulka and Miri 2003). They cite evidence of a hyper-aggregation with 80 percent of the biomass now concentrated in 20 percent of the area along the southwest slope of the Grand Banks (Kulka *et al.* 2007). As noted by Kulka *et al.* (2006), in the early 1980s, thorny skates were distributed over the entire Grand Banks in moderate to high concentrations, but by the late 1990s, much of the biomass was concentrated in the southwest. The proportion of the surveyed area containing no skates increased from about 2 percent in 1980 to 1988 to 22 percent in 2004 to 2005. During 1980 to 1988, about 57 percent of the biomass was located within 20 percent of the survey area, by 2001 to 2005, 78 percent of the biomass was concentrated into 20 percent of the survey area. Therefore, the area occupied by thorny skates has decreased, and the population has become increasingly more concentrated in a smaller area where bottom temperatures are warmest. A very similar pattern of aggregation was observed for northern cod just prior to its collapse (Rose and Kulka 1999). Kulka and Miri (2003) state that aggregation and reduced area of occupancy led to the cod being increasingly more vulnerable to exploitation and they state this is very similar to what is happening to thorny skate. They do acknowledge that it is unknown whether these spatial dynamics are an indication of a skate stock under stress. The 2007 update by Kulka and Miri noted that the species had shown a minor re-expansion in its distribution in the past 3 to 4 years.

Kulka and Miri (2006) noted that the average weight of thorny skate had declined from 2 kg in the early 1970s to 1.2 kg in 1996 with the majority of this decline occurring in the 1990s concurrent with the decline in biomass. They reported that average size had increased to about 1.6 kg since that time. They note that the decline of thorny skate, particularly on the

northern Grand Banks, is concurrent in space and time with the decline of many other demersal species and occurred during a period when bottom temperatures were below average.

In conclusion, in the southern part of its range in Canada, and in the United States, we find evidence suggesting that population abundance of thorny skate has continued to decline, and in the northern part of its range thorny skate may be stable at a diminished abundance. While data are still limited with respect to population size and trends, we find the petition and our files contain sufficient information on thorny skate trends and status to indicate that the petitioned action may be warranted.

#### Analysis of DPS Information

The petition requests that we list the thorny skate population in the Northwest Atlantic as a threatened or endangered DPS and presents arguments that thorny skate in the Northwest Atlantic meet the criteria to be considered a DPS, as described in the 1996 joint NMFS and the U.S. Fish and Wildlife Service DPS policy (61 FR 4722; February 7, 1996). Alternatively, the petition requests that we list the thorny skate population in the United States as a threatened or endangered DPS and presents arguments that thorny skate in U.S. waters meet requirements for being identified as a DPS eligible for listing. Our DPS policy identifies two elements that must be considered when identifying a DPS: (1) The discreteness of the population segment in relation to the remainder of the species (or subspecies) to which it belongs; and (2) the significance of the population segment to the species to which it belongs. A population segment of a vertebrate species may be considered discrete if it satisfies either one of the following conditions: (1) It is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors—quantitative measures of genetic or morphological discontinuity may provide evidence of this separation; or (2) it is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat conservation status, or regulatory mechanisms exist that are significant in light of section 4(a)(1)(D) of the ESA. If a population segment is considered discrete under one or more of the above conditions, its biological and ecological significance will then be considered in light of Congressional guidance (see Senate Report 151, 96th Congress, 1st Session) that the authority to list DPSs be used “sparingly” while encouraging

the conservation of genetic diversity. In carrying out this examination, the Services will consider available scientific evidence of the discrete population segment’s importance to the taxon to which it belongs. This consideration may include, but is not limited to, the following: (1) Persistence of the discrete population segment in an ecological setting unusual or unique for the taxon; (2) evidence that loss of the discrete population segment would result in a significant gap in the range of a taxon; (3) evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historic range; or (4) evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics.

The petitioners state the Northwest Atlantic thorny skate population, encompassing Canadian and U.S. waters, satisfies both the “discrete” and “significant” requirements for DPS identification. They state that the Northwest Atlantic population is discrete because it is markedly separated from other populations due to physical and biological factors.

The petitioners describe the results of tagging studies (Templeman 1984, Templeman 1987, Walker *et al.* 1997) and suggest that thorny skate are a relatively sedentary species in both the Northwest and Northeast Atlantic. They use the maximum distance traveled from a tagging location (386 km; Templeman 1984), the small portion of the tagged individuals that traveled more than 161 km (13 percent; Templeman 1984) in the Northwest Atlantic, the small portion of tagged individuals that traveled more than 93 km in the North Sea (15 percent; Walker *et al.* 1997), and the conclusions of Templeman (1987) that “large scale migrations did not occur” between the Grand Banks and Labrador Shelf to conclude that long distances may hinder thorny skates from embarking on long enough migrations to travel between the Northeast and Northwest Atlantic. The petitioners claim that there is no indication that a significant portion of the populations travel between the Northeast and Northwest Atlantic. These studies rely solely on conventional tagging data and only report the distance between the tagging location and the location of recapture. It is unknown if the maximum distances reported between tagging and recapture location are in fact reflective of the maximum normal or maximum possible migration distance. However, as noted in the 2015 petition, if this is

interpreted to mean that the maximum migration is 386 km, this is not far enough to allow for trans-Atlantic migration, and this could support the petitioner’s claim that separate, isolated Northwest and Northeast Atlantic populations of thorny skate exist.

The petitioners present some information on available genetic studies of thorny skate. They state that the findings of Coulson *et al.* (2011) suggest that genetic diversity may exist in thorny skate and that this is indicative of population structure. The petitioners also address the findings of Chevolet *et al.* (2007) and question the validity of Chevolet *et al.*’s conclusions. The results of Coulson *et al.* (2011) indicate that thorny skate showed the highest level of within-species divergence (0.8 percent) across all skate species from Atlantic Canada examined, but this was largely due to a single individual, collected off the Gulf of Maine, with 3–4 percent sequence divergence from the other thorny skates examined. Coulson *et al.* (2011) also note that, with the exception of one other species (for which only two samples were tested), thorny skate showed the highest levels of both haplotype and nucleotide diversity; this was true even when the Gulf of Maine sample was excluded.

The petitioners interpret Chevolet *et al.* (2007) to note that the near absence of genetic differentiation in thorny skate over the North Atlantic does not conform to predictions based on life history characteristics, and they acknowledge that the lack of power related to small sample size and the use of only one molecular marker might explain this. However, the authors note that a parallel study using the same marker for another skate species did find strong and highly significant structure at the ocean basin scale. The petitioners claim that this is not credible because the other study (Chevolet 2006) deals with a different skate species with different phylogeographic and population genetic structure patterns and because it does not minimize the problems associated with a small sample size. The only other information in our files is a study (Ostrow *et al.* 2008) that concluded there was no significant population structuring between phenotypically different thorny skate within the Gulf of Maine or between thorny skate samples from the Gulf of Maine and Canada. This suggests that mixing may occur between thorny skate in the Gulf of Maine and Canada. The authors also concluded that the number of migrants between the Gulf of Maine and Canada indicated large amounts of gene flow suggesting that genetic isolation had not occurred

between any of the groups. The petitioners also note a statement in COSEWIC (2012) that states that large morphological and reproductive differences among thorny skates in different areas in conjunction with indications of minimal migration suggest that there could be spatial variation in population structure.

The available genetic studies present conflicting information on the potential for significant differences between populations of thorny skate. We conclude that, viewed together, the genetics and tagging information presented in the petition combined with the information in our files present sufficient evidence that the DPS policy's criterion for discreteness may be met for the Northwest Atlantic population of thorny skate.

The petitioner argues that thorny skate in the Northwest Atlantic are significant because the loss of this population would result in a significant reduction in the species' range with no significant evidence that populations outside of this range could recolonize these waters. While not clearly stated, we presume the petitioners based this on the tagging information presented in their arguments for discreteness. The petitioners also claim that the separate assessments and classifications of the Northwest and Northeast Atlantic stocks of thorny skate by the IUCN are evidence that the populations are discrete and significant. The petitioners do not present any analysis to support the claim that the IUCN stock determination is equivalent to a determination that a population meets the significance criterion in the DPS policy. However, based on the tagging information, we conclude that the petition presents sufficient evidence that the DPS policy's criterion for significance, particularly the "significant gap" consideration, may be met for the Northwest Atlantic population of thorny skate. Because the Northwest population of thorny skate may qualify as a DPS, we will consider it a potentially listable entity for purposes of this 90-day finding, and whether the Northwest Atlantic population of thorny skate constitutes a DPS will receive further analysis in the status review.

The petition claims the thorny skate population in U.S. waters also satisfies the discreteness and significance criteria for DPS designation. The petition claims that the U.S. population is discrete, because it is delimited by international governmental boundaries (delineating the United States and Canada) and significant differences exist in the control of exploitation, conservation

status, and regulatory mechanisms. The petition presents information on differences in management regimes between the United States and Canada, notably that possession and landing of thorny skate is prohibited in the United States and a directed fishery occurs for thorny skate in Canada and suggests that regulatory mechanisms in Canada are inadequate. The petition also describes management by the Northwest Atlantic Fisheries Organization (NAFO), which sets catch limits for thorny skate in the Northwest Atlantic. The petitioners claim that evidence suggests that the U.S. DPS may be discrete because it is markedly separated from the Canadian population as a consequence of physical and/or ecological factors. To support this, the petitioners point to the hyper-aggregated population along the southwest slope of the Grand Banks in Canadian waters (Kulka *et al.* 2007) and the relatively concentrated populations of thorny skates in the Gulf of Maine and Georges Bank offshore strata in U.S. waters (NEFMC 2009). The petitioner argues that the thorny skate population in the United States is also significant because the loss of this population would result in a significant gap in the species' range. We find that the petition presents substantial evidence that the DPS policy's criteria for discreteness and significance may be met for the U.S. population of thorny skate. Because the U.S. population of thorny skate may qualify as a DPS, we will consider it a potentially listable entity for purposes of this 90-day finding, and whether the U.S. population of thorny skate constitutes a DPS will receive further analysis in the status review.

#### **Analysis of ESA Section 4(a)(1) Factors**

The petition provides information on all five factors but asserts that the continued survival of the thorny skate is endangered by three of the five factors specified in section 4(a)(1) of the ESA: (B) Overutilization for commercial, recreational, scientific, or educational purposes; (D) inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued existence.

#### *Overutilization for Commercial, Recreational, Scientific, or Educational Purposes*

Skates are harvested in two different fisheries, one for lobster bait and one for wings for food. The fishery for lobster bait is a more historical and directed skate fishery, involving vessels primarily from Southern New England ports that target a combination of little skates and to a much lesser extent, juvenile winter skates. The fishery for

skate wings evolved in the 1990s as skates were promoted as an underutilized species. The wing fishery involves a larger number of vessels located throughout the region. Vessels tend to catch skates when targeting other species like groundfish, monkfish, and scallops and land them if the price is high enough (NEFMC 2009).

Thorny skates in the Atlantic U.S. Exclusive Economic Zone have been managed under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by the New England Fishery Management Council's fishery management plan for the Northeast (NE) Skate Complex (Skate FMP) since September 2003. Since that time, possession and landing of thorny skates has been prohibited, but the survey biomass index has continued to decline. It is important to note that based on the limited productivity of this species (long-lived, late maturity, low fecundity, etc.), rebuilding to target levels (4.12 kg/tow) was estimated to take at least 25 years (*i.e.*, 2028) (NEFMC 2009). The thorny skate's low productivity makes it vulnerable to exploitation, but also suggests that the population is inherently slow to respond to fishery management efforts.

The petition states that population estimates for the thorny skate in Canadian waters indicate stable, but not increasing numbers, and in the waters of the United States, biomass indices have been declining for decades, despite the federal ban on the landing and possession of thorny skates since 2003. The petition claims that thorny skate populations have been historically exploited at unsustainable rates. They state that participation in the commercial skate wing fishery in the Northwest Atlantic has grown dramatically over the past 30 years. They cite the initiation of a directed skate fishery in Canada in 1994 and an increase in skate landings in U.S. waters between the early 1980s and 2007. The petitioners note that biomass indices in Canada indicate that the species is maintaining relatively stable population numbers at very low levels. They claim the thorny skate population in U.S. waters continues to decline and state that the lack of regulation prior to 2003 reduced the population. The petitioners claim that current, and historical, overfishing has deleterious effects on the species population in U.S. waters and is a significant factor in the species' continued decline.

The petitioners claim that reports of illegal thorny skate landings suggest that thorny skates are being exploited in the commercial wing market. They state

that in the United States prior to August 2014, skate landings were not required to be reported by species. They cite NEFMC (2009), reporting that thorny skate wings composed 6.7 percent and 3 percent of the sampled dockside landings of skate wings in Massachusetts and Maine, respectively, from 2006–2007. However, according to port sampler data provided by the NMFS Greater Atlantic Regional Fisheries Office's Analysis and Program Support Division, the occurrence of thorny skates in skate wing landings has been significantly reduced since 2006. Out of 50,653 skate wings sampled between 2007 and 2010, only 353 (0.7 percent) were identified as thorny skate wings. The available information does not suggest that illegal landings are impacting thorny skate populations to a degree that raises concern that the species may be at risk of extinction.

The petitioners acknowledge that in contrast to Canada's directed thorny skate fishery, in the United States, thorny skates are primarily taken as bycatch in groundfish trawl fisheries. They also acknowledge that the prohibition on retention of the species means fishermen are banned from possessing or landing thorny skates or their parts, and Federal regulations mandate the discard of any incidentally caught thorny skates. The petition cites the 2009 and 2010 Standardized Bycatch Reporting Methodology (SBRM; Wigley *et al.* 2011) reports, which indicate that roughly 70 percent of all skates caught in various fisheries were discarded. We reviewed the SBRM reports for later years (Wigley *et al.* 2015, 2014, 2013 and 2012); these reports indicate that 49–63 percent of skates caught between July 2010 and June 2014 were discarded. The petitioners claim the possibility of egregious mis- and under-reporting of skate discards. However, other than noting that only 10 percent of selected otter trawl vessel total trips were observed under the Northeast Fisheries Observer Program, the petitioners provide no substantial information to support this claim of mis-reporting or under-reporting of skate discards. The available information does not suggest that mis-reporting or under-reporting is impacting thorny skate populations to a degree that raises concern that the species may be at risk of extinction.

The petitioners cite an estimate of 3,594 tons of thorny skate discarded from otter trawl fisheries in U.S. waters from 2003–2010. The petitioners claim that post-discard mortality for thorny skate is high and exacerbates the thorny skate's population decline and critically threatens stock rebuilding efforts. The

petitioners cite Mandleman *et al.* (2013) as support for their claim of high post-discard mortality. This study indicates that while 72-hour post-discard mortality of a sample of individuals retained in captivity following cage trials was only 22 percent, the condition of many of the individual thorny skate was poor (52 percent injury rate at time of capture; most with listless appearance and lack of vigor at the end of the 72-hour period) and 7 day mortality was 66 percent. The authors note that the species may be less resilient than indicated by the 22 percent 72-hour mortality rate and cautions against the use of the 22 percent mortality rate in management. The effects of captivity on these mortality rates are unknown. Further review is necessary to determine if this level of fishery-related mortality is a threat to thorny skate, but we cannot discount it as a possible threat to the species.

Given the evidence of historical exploitation of the species and subsequent population declines, the continued bycatch of thorny skate, and the potentially high post-discard mortality rate, the information in the petition and in our files leads a reasonable person to conclude that the petitioned action may be warranted.

#### *Inadequacy of Existing Regulatory Mechanisms*

The petitioners claim that a general lack of species-specific identification, both on-boat and at landing, poses a significant threat to the thorny skate's survival in U.S. waters and that because thorny skate are a prohibited species, the likelihood that the landings are underreported is strong. They also state that misidentification and mislabeling is a problem. The petitioner states that positive species identification at landing is hindered because current regulations allow vessels to possess and/or land skates as wings only (wings removed from the body of the skate and the remaining carcasses discarded). The petitioners also state that the designation of thorny skates as "prohibited", "overfished" and "subject to overfishing" allows room for inconsistent enforcement of the law. The petition states that the existing regulatory mechanisms provided for in the 2003 FMP are ineffective.

As noted in the petition, in 2013, we determined that overfishing is occurring for thorny skate. The determination that overfishing is occurring is made when there is a decrease of more than 20 percent between two consecutive moving averages of the biomass index. The 2011–2013 3-year average biomass

index (0.12 kg/tow) is only 3 percent of the species' biomass target. This 3-year average index represents an approximately 33 percent decrease from the 2010–2012 3-year moving average (0.18 kg/tow). While not noted in the petition, in an August 2014 memorandum (August 22, 2014 memo from NEFSC to GARFO) we determined that based on new survey data collected through autumn 2013/spring 2014, thorny skate remained overfished and overfishing was still occurring. Because thorny skate are a long lived species, the species may be slow to respond to management measures. However, the determination that overfishing is occurring suggests that, despite the ban on possession or landing, fishing mortality is a threat that may warrant further consideration.

As noted in the petition, the framework for the FMP for the Northeast skate complex was adjusted in 2014 to implement a 30 percent reduction in the skate Acceptable Biological Catch (ABC). However, as noted in the petition, the **Federal Register** notice announcing the availability of Framework Adjustment 2 acknowledges that while these reductions in catch limits are expected to address the current overfishing status for winter skates (not its overfished condition), the New England Fishery Management Council intends to develop a new skate action in 2014 to address overfishing and rebuild overfished thorny skates. The petition correctly notes that the Framework Adjustment 2 was not designed to address overfishing of thorny skates and correctly notes that as of the date of the petition, no new management action for thorny skate has been proposed.

While the determinations that thorny skate is overfished and that overfishing is occurring do not alone indicate that the species may be at risk of extinction, thorny skate biomass in the United States continues to decline and appears to be at historically low levels, and information was presented suggesting that fishing may be a contributing factor to this decline. Based on the information presented in the petition as well as information in our files, we find that further evaluation of the adequacy of existing regulatory measures in the United States is needed.

While the historical lack of species-specific trends in landings and discards has hampered stock assessment efforts, recent data collection efforts have greatly improved our understanding of the species composition of the landings. As noted in the petition, in August 2014, the reporting standard was changed. Framework Adjustment 2 to

the Northeast Skate FMP requires all landings be reported by one of the seven specific skate species or by “little/winter skate” if an unknown mix of the two species exists. Thorny skate wings are easily distinguishable from legal winter skate wings with a minimal amount of training, and port samplers and enforcement agents have received this training. Landing of thorny skates may have been more frequent in the past, but it has been dramatically curtailed since the prohibition on possession went into effect. Mislabeling of skate products does not appear to be widespread at U.S. ports, but port agents and enforcement agents have been trained to correct mislabeling if they observe it. The only information on mislabeling presented in the petition was about one specimen from a seafood show in Brussels, Belgium, which we view as not relevant to a potential listing in the United States. We conclude that the petition does not present sufficient information to determine that issues with landings data, misidentification or mislabeling are impacting thorny skate populations to a degree that raises concern that the petitioned action may be warranted.

The petition also states that regulatory mechanisms in Canada are inadequate to protect thorny skate. They claim that by adopting NAFO’s suggested total allowable catch (TAC) limits for skate, Canada has implemented regulations that have not successfully promoted stock rebuilding. Finally, the petition also states that Canada lacks substantive protective regulatory mechanisms for thorny skate and has not afforded a conservation status by COSEWIC. As reported in the petition, thorny skate abundance indices have stabilized in Canadian waters in recent years while biomass indices have gradually increased (DFO 2013), but both indices are at historically low levels. The petitioners argue that while the average reported annual catch from NAFO Division 3LNO from 2009–2011 is less than half the current TAC, there has been minimal to no rebuilding of the stock during this period. The petitioners claim there are no indications the stock is recovering since it was brought under management and argue that both the current TAC (reported by the petitioners as 7,000 tons, citing NAFO 2012) and the reported average skate catches are too high to promote any stock recovery. The most recent stock assessment of thorny skate in NAFO Subdivision 3PS (inside Canada’s 200-mile limit) indicates the TAC has been continually reduced since 2004 (13,500 tons) and is currently at 8,500 t (DFO 2013). The

Canadian research survey abundance for Subdivision 3Ps was relatively stable from 1993–2012, while the survey biomass index indicated a gradually increasing trend (DFO 2013). In NAFO divisions 3LNO, Canadian research survey indices declined rapidly until the early 1990s; abundance indices were relatively stable in 1993–2012, while the survey biomass indices have generally been increasing (DFO 2013). DFO 2013 acknowledges that since the 1980s, thorny skate has undergone substantial changes in its distribution and has become increasingly aggregated in subdivision 3Ps, and on the southern part of the Grand Banks. They state that this results in a decreasing area of occupancy and increasing catch rates in commercial fisheries occurring in those aggregation areas. The report also indicates that discarding of skate bycatch at sea remains unreported by Canadian and other fishers, which results in higher removals of thorny skate than available fisheries statistics indicate and that commercial skate landings from Canada’s EEZ are not required to be reported by species. The report concludes that despite a number of years of reduced commercial landings, there was no recovery of thorny skate in the 3LNOPs stock area despite apparently stable abundance in the 3Ps portion and that biomass and abundance indices for the entire division 3LNO and subdivision 3Ps thorny skate stock area remain at relatively low levels. Based on the information presented in the petition as well as information in our files, we find that further evaluation of the adequacy of existing regulatory measures outside of the United States is needed. Given the information presented above, the information in the petition and in our files leads a reasonable person to conclude that the petitioned action may be warranted.

#### *Other Natural or Manmade Factors Affecting Its Existence*

The petition claims that global warming poses a long-term threat to Northwest Atlantic thorny skates and their recovery from depletion. They state that the documented global ocean warming trend could result in a change in species composition in northern waters which could adversely affect the thorny skate’s predator-prey dynamics or introduce new pathogens that could harm thorny skates. The petitioners provide information on sea surface temperatures and hydrography in the Gulf of Maine and state that one outcome will be reductions in phytoplankton productivity. While they state that changes at the lower levels of

the food web may have consequences to animals at higher trophic levels, they provide no information on the impacts of these changes on thorny skate. The petitioners have not provided substantial information indicating that potential impacts to lower levels of the food web are causing detrimental effects to thorny skate or may be contributing or may, in the foreseeable future, contribute significantly to population declines of thorny skate to the point where the petitioned action may be warranted.

They also state that global warming could result in a contraction of the range of cold-water species such as the thorny skate. They speculate that a range contraction could be a potential factor in the decrease in thorny skate biomass in the Gulf of Maine and that the amount of thermal habitat in the 5 to 15 °C range has decreased over the past two decades. The petitioners state that the majority of thorny skates are not capable of journeys of more than 96 km and the farthest an individual has been documented traveling is 386 km (citing Templeman 1984) and that, as such, a large-scale northern migration to move away from warming waters in the southern portion of their range appears unlikely. As noted above, it is unclear what the actual maximum migratory distance for a thorny skate is. The petitioners also claim that thorny skate have experienced a northward shift in the center of their biomass. More research is necessary to investigate if there is a correlation between Gulf of Maine water temperatures and thorny skate biomass, but the available information on thorny skate temperature preferences suggests that this could be a possibility.

There is uncertainty regarding the role of temperature in driving or contributing to the historical and current distribution and abundance of thorny skate and even greater uncertainty regarding potential future impacts of climate change. Impacts from climate change to habitat availability or suitability could pose particular problems for U.S. populations of thorny skate as they are at the southern extent of the range of the species and are at historically low levels of abundance. Further review is necessary to determine if climate change is a threat to thorny skate. Given the evidence of range contraction and the uncertainty regarding the role of warming ocean waters, we conclude that the information in the petition and in our files suggests that climate change, and warming ocean waters specifically, may be impacting thorny skate to a degree that raises concern over their continued

persistence and that should be further evaluated in a status review.

The petitioners claim that hypoxia (oxygen deficiency) has increased in frequency, duration, and severity in coastal waters and that this decreases the abundance and diversity of benthic macrofauna (citing CSIS 2011). They also claim that the combination of hypoxia and increased water temperature would reduce the quality and size of suitable habitat for aerobic organisms whose suitable habitat is restricted by water temperature and claim that thorny skate is such a species. While acknowledging that any prediction of the effects of hypoxic zones on thorny skates is speculative, the petitioners state that any adverse impact on the species or on the abundance/distribution of its predators or prey will severely hinder the species' ability to recover. However, neither the petitioners nor the information in our files indicate that thorny skate are impacted by hypoxia or that hypoxia may be contributing significantly to population declines in thorny skates to the point where the species may be at a risk of extinction. As such, we conclude that the information presented in the petition on the threat of hypoxia does not provide substantial information indicating that hypoxia may be impacting thorny skate to a degree that the petitioned action may be warranted.

The petitioners state that the life history characteristics of thorny skate place the species at risk of adverse effects resulting from natural stochastic events. However, neither the petitioners nor the information in our files indicate that natural stochastic events are causing detrimental effects to the species or may be contributing significantly to population declines in thorny skates to the point where the species may be at a risk of extinction. As such, we conclude that the information presented in the petition on the threat of natural stochastic events does not provide substantial information indicating that such events may be impacting or may, in the foreseeable future, impact thorny skate to a degree that the petitioned action may be warranted. However, given all of the information presented above on other natural and manmade factors, particularly the warming of oceans, the information in the petition and in our files does lead a reasonable person to conclude that the petitioned action may be warranted, and it is necessary to consider the impacts from other natural and manmade factors in a status review.

### Summary of ESA Section 4(a)(1) Factors

We conclude that the petition presents substantial scientific or commercial information indicating that a combination of three of the section 4(a)(1) factors (overutilization for commercial, recreational, scientific, or educational purposes; inadequate existing regulatory mechanisms; and other natural or manmade factors) may be causing or contributing to an increased risk of extinction for thorny skate which needs to be further evaluated in a review of the status of the species.

### Petition Finding

After reviewing the information contained in the petition, as well as information readily available in our files, and based on the above analysis, we conclude the petition presents substantial scientific information indicating the petitioned action of listing a Northwest Atlantic or United States DPS of thorny skate as threatened or endangered may be warranted. Therefore, in accordance with section 4(b)(3)(B) of the ESA and NMFS' implementing regulations (50 CFR 424.14(b)(2)), we will commence a review of the status of the species. During our status review, we will first determine whether one of the populations identified by the petitioners meets the DPS policy criteria, and if so, whether it is threatened or endangered throughout all or a significant portion of its range. We now initiate this review, and thus, the Northwest Atlantic population of the thorny skate is considered to be a candidate species (see 69 FR 19975; April 15, 2004). To the maximum extent practicable, within 12 months of the receipt of the petition (May 28, 2016), we will make a finding as to whether listing either of the populations identified by the petitioner as DPSs as endangered or threatened is warranted as required by section 4(b)(3)(B) of the ESA. If listing a DPS is found to be warranted, we will publish a proposed rule and solicit public comments before developing and publishing a final rule. The petitioners request that we designate critical habitat for thorny skates. ESA Section 4(a)(3)(A) and its implementing regulations state that, to the maximum extent prudent and determinable, the Secretary shall, concurrently with listing a species as endangered or threatened, designate any critical habitat for that species. If a thorny skate population were to be listed as a DPS, we would follow the relevant statutory and regulatory

provisions regarding the designation of critical habitat.

### Information Solicited

To ensure that the status review is based on the best available scientific and commercial data, we are soliciting information on the thorny skate. Specifically, we solicit information in the following areas: (1) Historical and current distribution and abundance of this species in the Northwest Atlantic; (2) historical and current population status and trends; (3) any current or planned activities that may adversely impact the species, especially as related to the five factors specified in section 4(a)(1) of the ESA and listed above; (4) ongoing efforts to protect and restore the species and its habitat; and (5) genetic data or other information related to possible population structure of thorny skate. We request that all information be accompanied by: (1) Supporting documentation such as maps, bibliographic references, or reprints of pertinent publications; and (2) the submitter's name, address, and any association, institution, or business that the person represents.

### References Cited

A complete list of references is available upon request (see **ADDRESSES**).

### Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: October 16, 2015.

### Samuel D. Rauch, III

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

[FR Doc. 2015-27147 Filed 10-23-15; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 224

[Docket No. 150209121-5941-02]

RIN 0648-XD760

### Endangered and Threatened Wildlife; 12-Month Finding on a Petition To Identify and Delist a Saint John River Distinct Population Segment of Shortnose Sturgeon Under the Endangered Species Act

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

**ACTION:** Notice of 12-month petition finding.

**SUMMARY:** We, NMFS, announce a 12-month finding on a petition to identify and “delist” shortnose sturgeon (*Acipenser brevirostrum*) within the Saint John River in New Brunswick, Canada under the Endangered Species Act (ESA). The shortnose sturgeon is currently listed as an endangered species, at the species level, under the ESA. Based on our review of the best scientific and commercial data available, we have determined that the population of shortnose sturgeon from the Saint John River does not qualify as a distinct population segment. Therefore, we did not consider the petition further, and we do not propose to delist this population.

**DATES:** This finding was made on October 26, 2015.

**ADDRESSES:** Information used to make this finding is available for public inspection by appointment during normal business hours at NMFS, Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910. The petition and the list of the references used in making this finding are also available on the NMFS Web site at: [www.nmfs.noaa.gov/pr/species/fish/shortnose-sturgeon.html](http://www.nmfs.noaa.gov/pr/species/fish/shortnose-sturgeon.html).

**FOR FURTHER INFORMATION CONTACT:** Lisa Manning, Office of Protected Resources, 301–427–8466; Stephania Bolden, Southeast Regional Office, 727–824–5312; Julie Crocker, Greater Atlantic Regional Office, 978–282–8480.

**SUPPLEMENTARY INFORMATION:**

**Background**

On September 24, 2014, we received a petition from Dr. Michael J. Dadswell, Dr. Matthew K. Litvak, and Mr. Jonathan Barry regarding the population of shortnose sturgeon (*Acipenser brevirostrum*) native to the Saint John River in New Brunswick, Canada. The petition requests that we identify the Saint John River population of shortnose sturgeon as a distinct population segment (DPS) and contemporaneously “delist” this DPS by removing it from the species-wide listing under the Endangered Species Act. On April 6, 2015, we published a positive finding indicating that the petitioned action may be warranted and that we were initiating a status review to consider the petition further (80 FR 18347).

The shortnose sturgeon was originally listed as an endangered species throughout its range by the U.S. Fish and Wildlife Service (USFWS) on March 11, 1967, under the Endangered Species

Preservation Act (ESPA, 32 FR 4001). Shortnose sturgeon remained on the endangered species list when the U.S. Congress replaced the ESPA by enacting the Endangered Species Conservation Act of 1969, which was in turn replaced by the Endangered Species Act of 1973 (ESA, 16 U.S.C. 1531 *et seq.*). We subsequently assumed jurisdiction for shortnose sturgeon under a 1974 government reorganization plan (39 FR 41370, November 27, 1974). In Canada, the shortnose sturgeon falls under the jurisdiction of the Department of Fisheries and Oceans (DFO) and was first assessed by the Committee on the Status of Endangered Wildlife in Canada (COSEWIC) as “Special Concern” in 1980. This status was reconfirmed in 2005, and the species was listed as Special Concern under the Canadian federal Species at Risk Act (SARA) in 2009. The Special Concern status was reconfirmed again in 2015 (COSEWIC, In Press). Shortnose sturgeon is also listed under Appendix I of the Convention on International Trade in Endangered Species of Wild Fauna (CITES).

**Statutory, Regulatory and Policy Provisions**

We are responsible for determining whether species are threatened or endangered under the ESA (16 U.S.C. 1531 *et seq.*). To make this determination, we first consider whether a group of organisms constitutes a “species” under section 3 of the ESA, and then we consider whether the status of the species qualifies it for listing as either threatened or endangered. Section 3 of the ESA defines a “species” to include “any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature” (16 U.S.C. 1532(16)). A joint policy issued by NMFS and the U.S. Fish and Wildlife Service (USFWS; collectively referred to as “the Services”) clarifies the interpretation of the phrase “distinct population segment” (DPS) for the purposes of listing, delisting, and reclassifying a species under the ESA (“DPS Policy,” 61 FR 4722, February 7, 1996). The DPS Policy identifies two criteria for determining whether a population is a DPS: (1) The population must be “discrete” in relation to the remainder of the taxon (species or subspecies) to which it belongs; and (2) the population must be “significant” to the remainder of the taxon to which it belongs.

Congress has instructed the Secretary to exercise the authority to recognize DPS’s “sparingly and only when the

biological evidence indicates that such action is warranted” (S. Rep. 96–151 (1979)). The law is not settled as to the extent of the Services’ discretion to modify a species-level listing to recognize a DPS having a status that differs from the original listing. In a recent decision, the United States District Court for the District of Columbia held that the ESA does not permit identification of a DPS solely for purposes of delisting. *Humane Soc’y v. Jewell*, 76 F. Supp. 3d 69 (D.D.C. Dec. 19, 2014), *appeal docketed*, No. 15–5041 (D.C. Cir. Feb. 19, 2015) (Western Great Lakes gray wolves) (consolidated with Nos. 15–5043, 15–5060, and 15–5061).

A species, subspecies, or DPS is “endangered” if it is in danger of extinction throughout all or a significant portion of its range, and “threatened” if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range (ESA sections 3(6) and 3(20), respectively, 16 U.S.C. 1532(6) and (20)). We interpret an “endangered species” to be one that is presently in danger of extinction. A “threatened species,” on the other hand, is not presently in danger of extinction, but is likely to become so in the foreseeable future. In other words, the primary statutory difference between a threatened and endangered species is the timing of when a species may be in danger of extinction, either presently (endangered) or in the foreseeable future (threatened). In addition, we interpret “foreseeable future” as the horizon over which predictions about the conservation status of the species can be reasonably relied upon.

Pursuant to the ESA and our implementing regulations, the determination of whether a species is threatened or endangered shall be based on any one or a combination of the following five section 4(a)(1) factors: The present or threatened destruction, modification, or curtailment of habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; inadequacy of existing regulatory mechanisms; and any other natural or manmade factors affecting the species’ existence. 16 U.S.C. 1533(a)(1); 50 CFR 424.11(c). Listing determinations must be based solely on the best scientific and commercial data available, after conducting a review of the species’ status and after taking into account any efforts being made by any state or foreign nation (or any political subdivision of such state or foreign nation) to protect the species. 16 U.S.C. 1532(b)(1)(A).



Under section 4(a)(1) of the ESA and the implementing regulations at 50 CFR 424.11(d), a species shall be removed from the list if the Secretary of Commerce determines, based on the best scientific and commercial data available after conducting a review of the species' status, that the species is no longer threatened or endangered because of one or a combination of the section 4(a)(1) factors. The regulations provide that a species listed under the ESA may be delisted only if such data substantiate that it is neither endangered nor threatened for one or more of the following reasons:

(1) *Extinction*. Unless all individuals of the listed species had been previously identified and located, and were later found to be extirpated from their previous range, a sufficient period of time must be allowed before delisting to indicate clearly that the species is extinct.

(2) *Recovery*. The principal goal of the USFWS and NMFS is to return listed species to a point at which protection under the ESA is no longer required. A species may be delisted on the basis of recovery only if the best scientific and commercial data available indicate that it is no longer endangered or threatened.

(3) *Original data for classification in error*. Subsequent investigations may show that the best scientific or commercial data available when the species was listed, or the interpretation of such data, were in error. 50 CFR 424.11(d).

To complete the required finding in response to the current delisting petition, we first evaluated whether the petitioned entity meets the criteria of the DPS Policy. As we noted in our initial petition finding, a determination whether to revise a species-level listing to recognize one or more DPSs in place of a species-level listing involves, first,

determining whether particular DPS(s) exist(s) (based on meeting the criteria of the DPS Policy) and, if that finding is affirmative, complex evaluation as to the most appropriate approach for managing the species in light of the purposes and authorities under the ESA.

#### Species Description

Below, we summarize basic life history information for shortnose sturgeon. A more thorough discussion of all life stages, reproductive biology, habitat use, abundance estimates and threats are provided in the Shortnose Sturgeon Biological Assessment completed by the Shortnose Sturgeon Status Review Team in 2010 (SSRT 2010; <http://www.fisheries.noaa.gov/pr/species/fish/shortnose-sturgeon.html>).

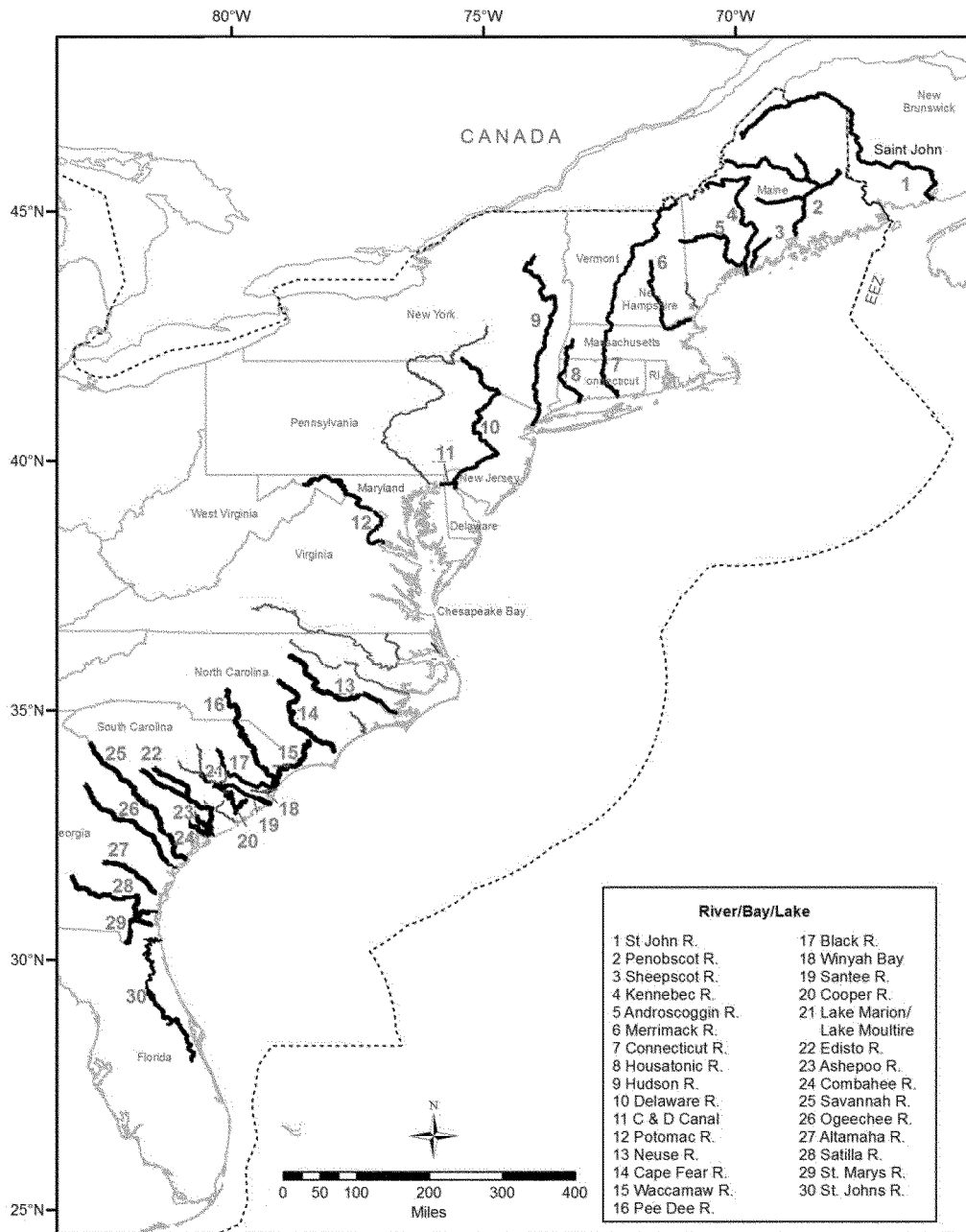
There are 25 species and four recognized genera of sturgeons (family Acipenseridae), which comprise an ancient and distinctive assemblage with fossils dating to at least the Upper Cretaceous period, more than 66 million years ago (Findeis 1997). The shortnose sturgeon, *Acipenser brevirostrum*, is the smallest of the three extant sturgeon species in eastern North America. Many primitive physical characteristics that reflect the shortnose sturgeon's ancient lineage have been retained, including a protective armor of bony plates called "scutes"; a subterminal, protractile tube-like mouth; and chemosensory barbels. The general body shape is cylindrical, tapering at the head and caudal peduncle, and the upper lobe of the tail is longer than the lower lobe. Shortnose sturgeon vary in color but are generally dark brown to olive or black on the dorsal surface, lighter along the row of lateral scutes, and nearly white

on the ventral surface. Adults have no teeth but possess bony plates in the esophagus that are used to crush hard prey items (Vladykov and Greeley 1963; Gilbert 1989). The skeleton is almost entirely cartilaginous with the exception of some bones in the skull, jaw and pectoral girdle.

Shortnose sturgeon occur along the East Coast of North America in rivers, estuaries, and marine waters. Historically, they were present in most major rivers systems along the Atlantic coast (Kynard 1997). Their current riverine distribution extends from the Saint John River, New Brunswick, Canada, to possibly as far south as the St. Johns River, Florida (Figure 1; Kynard 1997; Gorham and McAllister 1974). Recently available information indicates that their marine range extends farther northward than previously thought and includes the Minas Basin, Nova Scotia (Dadswell *et al.* 2013). The distribution of shortnose sturgeon across their range, however, is disjunct, with no known reproducing populations occurring within the roughly 400 km of coast between the Chesapeake Bay and the southern boundary of North Carolina. Shortnose sturgeon live in close proximity with Atlantic sturgeon (*Acipenser oxyrinchus oxyrinchus*) throughout much of their range. However, Atlantic sturgeon spend more of their life cycle in the open ocean compared to shortnose sturgeon. Within rivers, shortnose sturgeon and Atlantic sturgeon may share foraging habitat and resources, but shortnose sturgeon generally spawn farther upriver and earlier than Atlantic sturgeon (Kynard 1997, Bain 1997).

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**Figure 1.** Major river systems within the currently or potentially occupied range of shortnose sturgeon.

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Shortnose sturgeon typically migrate seasonally between upstream freshwater spawning habitats and downstream foraging mesohaline (*i.e.*, salinities of 5 to 18 parts per thousand) habitat based on water temperature, flow, and salinity cues. Based on their varied and complex use of freshwater, estuarine, and marine waters, shortnose sturgeon have been characterized in the literature as “anadromous” or “amphidromous” (Bain 1977; Kieffer and Kynard 1993). An anadromous species is defined as

one that spawns in freshwater and spends much of its life cycle in marine waters, whereas a freshwater amphidromous species is one that spawns and remains in freshwater for most of its life cycle but spends some time in saline water. Because shortnose sturgeon had historically rarely been detected far from their natal estuary, they were once considered to be largely confined to their natal rivers and estuaries (NMFS 1998). However, more recent research has demonstrated that shortnose sturgeon leave their natal

estuaries, undergo coastal migrations, and use other river systems to a greater extent than previously thought (Kynard 1997; Savoy 2004; Fernandes 2010; Zydlewski *et al.* 2011; Dionne *et al.* 2013). The reasons for inter-riverine movements are not yet clear, and the degree to which this behavior occurs appears to vary among river systems.

Shortnose sturgeon are benthic feeders, and their diet typically consists of small insects, crustaceans, mollusks, polychaetes, and small benthic fishes (McCleave *et al.* 1977; Dadswell 1979;

Marchette and Smiley 1982; Dadswell *et al.* 1984; Moser and Ross 1995; Kynard *et al.* 2000; Collins *et al.* 2002). Both juvenile and adult shortnose sturgeon primarily forage over sandy-mud bottoms, which support benthic invertebrates (Carlson and Simpson 1987, Kynard 1997). Shortnose sturgeon have also been observed feeding off plant surfaces (Dadswell *et al.* 1984). Sturgeon likely use electroreception, olfaction, and tactile chemosensory cues to forage, while vision is thought to play a minor role (Miller 2004).

Foraging in the colder rivers in the northern part of their range appears to greatly decline or cease during winter months when shortnose sturgeon generally become inactive. In mid-Atlantic areas, including the Chesapeake Bay, and the Delaware River, foraging is believed to occur year-round, though shortnose sturgeon are believed to feed less in the winter (J. O'Herron, Amitrone O'Herron, Inc., pers. comm. 2008 as cited in SSRT 2010). In the southern part of their range, shortnose sturgeon are known to forage widely throughout the estuary during the winter, fall, and spring (Collins and Smith 1993, Weber *et al.* 1999). During the hotter months of summer, foraging may taper off or cease as shortnose sturgeon take refuge from high water temperatures.

Shortnose sturgeon are relatively small compared to most extant sturgeon species and reach a maximum length of about 120 cm total length (TL) and weight of about 24 kg (Dadswell 1979; Waldman *et al.* 2002); however, both maximum size and growth rate display a pattern of gradual variation across the range, with the fastest growth rates and smallest maximum sizes occurring in the more southern populations (Dadswell *et al.* 1984). The northernmost populations exhibit the slowest growth and largest adult sizes. The largest shortnose sturgeon reported in the published literature to date was collected from the Saint John River, Canada, and measured 143cm TL (122 cm fork length (FL)) and weighed 23.6 kg (Dadswell 1979). In contrast, in their review, Dadswell *et al.* (1984) indicated that the largest adult reported from the St. Johns River, Florida, was a 73.5 cm (TL) female. Dadswell *et al.* (1984) compared reported growth parameters across the range and showed that the von Bertalanffy growth parameter K and estimated asymptotic length ranged from 0.042 and 130.0 cm (FL), respectively, for Saint John River fish to 0.149 and 97.0 cm (FL) for Altamaha River, Georgia fish. However, the land-locked shortnose sturgeon population located upstream of Holyoke Dam at

river km 140 of the Connecticut River has the slowest adult growth rate of any surveyed, which may at least in part reflect food limitations (Taubert 1980a).

Shortnose sturgeon are relatively long-lived and slow to mature. The oldest shortnose sturgeon reported was a 67 year-old female from the Saint John River, and the oldest male reported was a 32 year-old fish, also captured in the Saint John River (Dadswell 1979). In general, fish in the northern portion of the species' range live longer than individuals in the southern portion of the species' range (Gilbert 1989). Males and females mature at about the same length, around 45–55 cm FL, throughout their range (Dadswell *et al.* 1984). However, age at maturity varies by sex and with latitude, with males in the southern rivers displaying the youngest ages at maturity (see review in Dadswell *et al.* 1984). For example, age at first maturation in males occurs at about 2–3 years of age in Georgia and at about 10–11 years in the Saint John River. Females mature by 6 years of age in Georgia and at about 13 years in the Saint John River (Dadswell *et al.* 1984).

Sturgeon are iteroparous, meaning they reproduce more than once during their lifetime. In general, male shortnose sturgeon are thought to spawn every other year, but they may spawn annually in some rivers (Dovel *et al.* 1992; Kieffer and Kynard 1996). Females appear to spawn less frequently—approximately every 3 to 5 years (Dadswell 1979). Spawning typically occurs during late winter/early spring (southern rivers) and mid-to-late spring (northern rivers) (Dadswell 1979, Taubert 1980a and b, Kynard 1997). The onset of spawning may be cued by decreasing river discharge following the peak spring freshet, when water temperatures range from 8 to 15 °C and bottom water velocities range between 25–130 cm/s, although photoperiod (or day-length) appears to control spawning readiness (Dadswell *et al.* 1984; Kynard *et al.* 2012). Spawning appears to occur in the sturgeons' natal river, often just below the fall line at the farthest accessible upstream reach of the river (Dovel 1981; Buckley and Kynard 1985; Kieffer and Kynard 1993; O'Herron *et al.* 1993; Kieffer and Kynard 1996). Following spawning, adult shortnose sturgeon disperse quickly down river and typically remain downstream of their spawning areas throughout the rest of the year (Buckley and Kynard 1985, Dadswell *et al.* 1984; Buckley and Kynard 1985; O'Herron *et al.* 1993).

In a review by Gilbert (1989), fecundity of shortnose sturgeon was reported to range between approximately 30,000–200,000 eggs per

female. Shortnose sturgeon collected from the Saint John River had a range of 27,000–208,000 eggs and a mean of 11,568 eggs/kg body weight (Dadswell 1979). Development of the eggs and transition through the subsequent larval, juvenile and sub-adult life stages are discussed in more detail in SSRT 2010.

A total abundance estimate for shortnose sturgeon is not available. However, population estimates, using a variety of techniques, have been generated for many individual river systems. In general, northern shortnose sturgeon population abundances are greater than southern populations (Kynard 1997). The Hudson River shortnose sturgeon population is currently considered to be the largest extant population (61,000 adults, 95 percent CI: 52,898–72,191; Bain *et al.* 2007; however, see discussion of this estimate in SSRT 2010). Available data suggest that some populations in northern rivers have increased over the past several decades (*e.g.*, Hudson, Kennebec; Bain *et al.* 2000; Squiers 2003) and that others may be stable (*e.g.*, Delaware; Brundage and O'Herron 2006). South of Chesapeake Bay, populations are relatively small compared to the northern populations. The largest population of shortnose sturgeon in the southern part of the range is from the Altamaha River, which was most recently estimated at 6,320 fish (95% CI: 4387–9249; Devries 2006). Occasional observations of shortnose sturgeon have been made in some rivers where shortnose sturgeon are considered extirpated (*e.g.*, St. Johns, St. Mary's, Potomac, Housatonic, and Neuse rivers); the few fish that have been observed in these rivers are generally presumed to be immigrants from neighboring basins.

The most recent total population estimate for the Saint John River dates to the 1970's. Using tag recapture data from 1973–1977, Dadswell (1979) calculated a Jolly-Seber population estimate of 18,000 ( $\pm 30\%$  SE; 95 percent CI: 7,200–28,880, COSEWIC, In Press) adults ( $\leq 50$  cm) below the Mactaquac Dam. Several partial population estimates are also available for the Kennebecasis River, a tributary in the lower reaches of the Saint John River. Litvak (unpublished data) calculated a Jolly-Seber estimate of 2,068 fish (95% CI: 801–11,277) in the Kennebecasis using mark-recapture data from 1998 to 2004 (COSEWIC, In Press). Based on videotaping of overwintering aggregations of shortnose sturgeon on the Kennebecasis River at the confluence of the Hammond River (rkm 35), Li *et al.* (2007) used ordinary Kriging to estimate that 4,836 (95% CI:

4,701–4,971) adult shortnose sturgeon were overwintering in that area. Usvyatsov *et al.* (2012) repeated this sampling in 2009 and 2011 and, using three different modeling techniques, estimated a total of 3,852–5,222 shortnose sturgeon in the study area, which suggests fairly stable abundance and habitat use at this site.

Threats that contributed to the species' decline and led to the listing of shortnose sturgeon under the ESA included pollution, overfishing, and bycatch in the shad fishery (USDOI 1973). Shortnose sturgeon were also thought to be extirpated, or nearly so, from most of the rivers in their historical range (USDOI 1973). In the late nineteenth and early twentieth centuries, shortnose sturgeon were commonly harvested incidental to Atlantic sturgeon, the larger and more commercially valuable of these two sympatric sturgeon species (NMFS 1998). Although there is currently no legal directed fishing for shortnose sturgeon in the United States, poaching is suspected, and bycatch still occurs in some areas. In particular, shortnose sturgeon are caught incidentally by bass anglers and in the alewife/gaspereau, American shad, American eel, and Atlantic sturgeon fisheries in the Saint John River; and shad fisheries in the Altamaha River, Santee River, Savannah River, and elsewhere (COSEWIC, In Press; SSRT 2010; Bahn *et al.* 2009; COSEWIC 2005). The construction of dams has also resulted in substantial loss of historical shortnose sturgeon habitat in some areas along the Atlantic seaboard. The construction and operation of dams can impede upstream movement to sturgeon spawning habitat (*e.g.*, Connecticut River, Santee River). Remediation measures, such as dam removal or modification to allow for fish passage have improved access in some rivers, and additional similar restoration efforts are being considered in other areas (*e.g.*, possible removal of the Mactaquac dam in the Saint John River). Other possible and ongoing threats include operation of power generating stations, water diversion projects, dredging, and other in-water activities that impact habitat.

#### Distinct Population Segment Analysis

The following sections provide our analysis of whether the petitioned entity—the Saint John River population of shortnose sturgeon—qualifies as a DPS of shortnose sturgeon (whether it is both “discrete” and “significant”). To complete this analysis we relied on the best scientific and commercial data available and considered all relevant literature and public comments

submitted in response to our 90-day finding (80 FR 18347, April 6, 2015).

For purposes of this analysis, we defined the Saint John River population segment of shortnose sturgeon to consist of shortnose sturgeon spawned in the Saint John River downstream of the Mactaquac Dam. Prior to construction of Mactaquac Dam in 1968/1969, sturgeon occurred upstream of the dam; however, it is unclear whether these were shortnose and/or Atlantic sturgeon and whether any sturgeon are still present upstream of the dam (COSEWIC, In Press). Lacking this information, we cannot consider fish that may be present upstream of the dam in our distinct population segment analysis. Throughout our discussion below we also use the term “population” to refer collectively to all shortnose sturgeon that are presumed to be natal to a particular river rather than using this term to refer strictly to a completely closed reproductive unit.

#### Discreteness Criterion

The Services' joint DPS Policy states that a population segment of a vertebrate species may be considered discrete if it satisfies either one of the following conditions:

(1) It is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors. Quantitative measures of genetic or morphological discontinuity may provide evidence of this separation.

(2) It is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant in light of section 4(a)(1)(D) of the ESA (61 FR 4722, February 7, 1996).

There are no physical barriers preventing the movement of Saint John River shortnose sturgeon outside of the Saint John River estuary or along the coast. The Mactaquac Dam, located about 140 km upstream and at the head of tide (Canadian Rivers Institute 2011), is the first upstream physical barrier on the Saint John River. This and other dams on the Saint John River block shortnose sturgeon from accessing upstream habitats, but there are no dams or other physical barriers separating Saint John River sturgeon from other shortnose sturgeon populations.

As mentioned previously, shortnose sturgeon have been documented to leave their natal river/estuary and move to other rivers to varying extents across their range. For example, telemetry data generated by Zydlewski *et al.* (2011) during 2008–2010 indicate that inter-

riverine movements of adult shortnose sturgeon occur fairly frequently among rivers in Maine. Seventy percent of tagged adults (25 of 41 fish) moved between the Penobscot and Kennebec rivers (about 150 km away), and up to 52% of the coastal migrants (13 of 25 fish) also used other, smaller river systems (*i.e.*, Damariscotta, Medomak, St. George) between the Penobscot and Kennebec rivers (Zydlewski *et al.* 2011). Shortnose sturgeon are also known to move between rivers in Maine and (*e.g.*, Kennebec, Saco) and the Merrimack River estuary in Massachusetts, traveling distances of up to about 250 km (as measured by a conservative, direct path distance; Little *et al.* 2013; Wippelhauser *et al.* 2015). At the other end of the range, in the Southeast United States, inter-riverine movements appear fairly common and include movements between the Savannah River and Winyah Bay and between the Altamaha and Ogeechee rivers (Peterson and Farrae 2011; Post *et al.* 2014).

Many inter-riverine movements have been observed elsewhere within the species' range, but patterns are not yet well resolved. For example, some shortnose sturgeon captured and/or tagged in the Connecticut River have been recaptured, detected, or were previously tagged in the Housatonic River (T. Savoy, CT DEP, pers. comm. 2015), the Hudson River (Savoy 2004), and the Merrimack River (M. Kieffer, USGS, pers. comm. 2015). At this time, the available tagging and tracking information is too limited to determine if Hudson River and Connecticut River shortnose sturgeon are making regular movements outside of their natal rivers and whether movement as far as the Merrimack River is a normal behavior. Movement data from the Chesapeake Bay is also relatively limited, but existing data indicate that shortnose sturgeon do move from the Chesapeake Bay through the Chesapeake and Delaware Canal into the Delaware River (Welsh *et al.* 2002).

The distances of the reported marine migrations vary widely from very short distances—such as between the Santee River and Winyah Bay, which are only about 15 km apart—to fairly long—as in the case of movements between the Merrimack and the Penobscot rivers, which are about 339 km apart at their mouths.<sup>1</sup> In general, the available data

<sup>1</sup> Distances between rivers mouths reported here were measured in GIS using the NOAA Medium Resolution Vector Shoreline, 20m bathymetry contour, and a fixed scale of 1:250,000. Estimated distances reported are the average of three, independently drawn and measured paths for each river pair. The assumed travel path between river mouths was the shortest possible distance that

suggest that movements between geographically proximate rivers are more common, while movements between more distant rivers do not, or only rarely, occur. A detailed discussion of the physical movements of shortnose sturgeon is provided in SSRT 2010.

The extent of coastal movements of shortnose sturgeon from the Saint John River is currently unknown (COSEWIC, In Press); however, some limited data are available and provide some insight into whether these fish may be geographically isolated from other populations. Any movement between Saint John River sturgeon and the nearest population in the Penobscot River would require a marine migration of about 362 km, a similar travel distance as between the Merrimack and the Penobscot rivers (340 km) and between the Connecticut and Merrimack rivers (348 km).<sup>2</sup> Dadswell (1979) reported that of 121 marked Saint John River shortnose sturgeon recaptured by commercial fisherman, 13 fish (11 percent) were recaptured in the Bay of Fundy, indicating that a portion of the population migrated into the marine environment. In addition, a confirmed shortnose sturgeon was caught in a fishing weir in the Minas Basin, off the coast of Nova Scotia about 165 km north of the mouth of the Saint John River (Dadswell *et al.* 2013). Fishermen in the Minas Basin also claim to catch about one to two shortnose sturgeon per year in their weirs (Dadswell *et al.* 2013). While it is plausible that the shortnose sturgeon captured in the Minas Bay originated from the Saint John River, data to confirm this are not available. In contrast, limited telemetry data suggest that movements outside of the Saint John River are not common. Of 64 shortnose sturgeon tagged in the Saint John River over the course of about 16 years from 1999 to 2015, none have been detected moving past the farthest downriver acoustic receiver located near the Saint John Harbor Bridge (M. Litvak, pers. comm. July 31, 2015).

Overall, while there is unambiguous evidence that shortnose sturgeon from the Saint John River leave the estuary—at least occasionally—and use the marine environment, and that shortnose sturgeon are capable of making long distance movements between river

systems, there are no available data on coastal migrations of Saint John River shortnose sturgeon. To date, there are also no reported observations or detections of shortnose sturgeon from the Gulf of Maine rivers moving into the Saint John River. Thus, while it is possible that the Saint John River shortnose sturgeon come in contact with shortnose sturgeon from elsewhere, it is also likely that some degree of geographical isolation by distance is occurring.

Although acoustic telemetry studies have revealed that shortnose sturgeon leave their natal river systems to a much greater extent than previously thought, such movements do not necessarily constitute permanent emigration or indicate interbreeding of populations. Tagging and telemetry studies within several river systems have provided evidence that shortnose sturgeon in those particular systems tend to spawn in their natal river (*e.g.*, Dovel 1981; Buckley and Kynard 1985; Kieffer and Kynard 1993; O'Herron *et al.* 1993; Kieffer and Kynard 1996). Tag return data for shortnose sturgeon in the Saint John River over the course of a 4-year study completed by Dadswell (1979) suggests there is little emigration from this system as well, and that spawning takes place in the freshwater sections of the upper estuary. The high site fidelity to natal rivers suggested by this and other studies indicates a there is a possible behavioral mechanism for the marked separation of the Saint John River population of shortnose sturgeon from other populations of the species.

A substantial amount of genetic data has become available since the "Final Recovery Plan for Shortnose Sturgeon" was developed in 1998. Below, we summarize the best available genetic data and information, which informed our evaluation of the "discreteness" of the Saint John River population segment. A more in-depth presentation of genetic data, including discussions of types of analyses and assumptions, is available in the Biological Assessment (SSRT 2010).

Much of the published information on population structure for shortnose sturgeon has been based on the genetic analysis of the maternally inherited mitochondrial DNA (mtDNA) due in part to the difficulties of analyzing data from the polyploid nuclear genome (Waldman *et al.* 2008). The analyses have focused on a moderately polymorphic 440 base pair portion of the mtDNA control region—a relatively rapidly evolving region of mtDNA and thus a good indicator of population-level differentiation. Haplotype frequencies and sequence divergence

data have consistently indicated an overall isolation-by-distance pattern of genetic population structure across the species' range, meaning that populations of shortnose sturgeon inhabiting rivers and embayments that are geographically more distant tend to be less related than those that are geographically closer (*e.g.*, Walsh *et al.* 2001, Grunwald *et al.* 2002, Waldman *et al.* 2002, and Wirgin *et al.* 2005; Wirgin *et al.* 2009). The haplotypes observed are typically shared across two to four or more adjacent sampled rivers but with little sharing of haplotypes between northern and southern populations (Waldman *et al.* 2002; Wirgin *et al.* 2009). Results for the Saint John River are compatible with these general patterns. For example, in the largest study to date, Wirgin *et al.* (2009) observed eight haplotypes within the Saint John River sample (n=42); and of the eight observed haplotypes, one was exclusive (or "private") to the Saint John River (and observed in 1 of 42 fish), and the remaining haplotypes were shared with two to six other rivers. None of the shared haplotypes were observed in samples south of the Chesapeake Bay. A previously unreported haplotype was recently observed in 2 of 15 shortnose caught from the Kennebecasis River, a tributary of the Saint John (Kerr, 2015; P. Wilson, public comment, May 2015). This new haplotype could indicate an even greater degree of differentiation of the Saint John River fish; however, no other rivers were sampled or analyzed as part of this study.

Despite the localized sharing of haplotypes, frequencies of the observed haplotypes are significantly different in most pairwise comparisons of the rivers sampled (*i.e.*, comparisons of haplotype frequencies from samples from two rivers), including many adjacent rivers (Wirgin *et al.* 2009). Such pairwise comparisons for the Saint John River in particular have indicated that this population is genetically distinct from the geographically closest sampled populations, including the Penobscot, Kennebec, and Androscoggin rivers (Grunwald *et al.* 2002; Waldman *et al.* 2002; Wirgin *et al.* 2005; Wirgin *et al.* 2009). For example, Wirgin *et al.* (2009) reported significant differences ( $p < 0.0005$ ) in haplotype frequencies between Saint John River shortnose sturgeon (n=42) and Penobscot (n=44, Chi-square=37.22), Kennebec (n=54, Chi-square=54.85), and Androscoggin (n=48, Chi-square=37.91) river samples. The level of genetic differentiation between the Saint John River population and the Penobscot, Kennebec, and

followed the general outline of the coast and was constrained by the 20m bathymetry contour, except where the shortest travel path across a deep, narrow inlet or bay crossed the 20m bathymetry contour.

<sup>2</sup>Distances reported here were measured following the same methods described in the previous footnote. The distance reported between the Connecticut and Merrimack River assumes a travel path via the Cape Cod Canal. A travel path around Cape Cod would instead result in a marine migration of about 560 km.

Androscoggin rivers also appears substantial, with  $\Phi_{ST}$  values ranging from 0.213 to 0.291 (where  $\Phi_{ST}$  ranges from 0 to 1, with 1 indicating complete isolation; Wirgin *et al.* 2009).

Estimates of female-mediated gene flow between the Saint John River and the Gulf of Maine rivers are fairly low. Wirgin *et al.* (2009) estimated female-mediated gene flow between the Saint John River and other Gulf of Maine rivers as 1.90–2.85 female migrants per generation based on  $\Phi_{ST}$  values, and as 1.5–1.9 females per generation in a separate, coalescent-based analysis. This result suggests that (if model assumptions are true) no more than three female shortnose sturgeon from the Saint John River are likely to spawn in the other Gulf of Maine rivers (or vice versa) per generation. These results provide additional evidence that the degree of female-based reproductive exchange between the Saint John River population and other nearby shortnose river populations has been relatively limited over many generations.

More recently, King *et al.* (2014) completed a series of analyses using nuclear DNA (nDNA) samples from 17 extant shortnose sturgeon populations across the species range. In contrast to the maternally inherited mtDNA, nDNA reflects the genetic inheritance from both the male and female parents. King *et al.* (2014) surveyed the samples at 11 polysomic microsatellite DNA loci and then evaluated the 181 observed alleles as presence/absence data using a variety of analytical techniques. The population structuring revealed by these analyses is consistent with the previous mtDNA analyses in that they also indicate a regional scale isolation-by-distance pattern of genetic differentiation. Analysis of genetic distances among individual fish (using principle coordinate analysis, PCO) revealed that the sampled fish grouped into one of three major geographic units: (1) Northeast, which included samples from the Saint John, Penobscot, Kennebec, Androscoggin, and Merrimack rivers; (2) Mid-Atlantic, which included samples from the Connecticut, Hudson, and Delaware rivers, as well as the Chesapeake Bay proper; and (3) Southeast, which included samples from the Cape Fear River, Winyah Bay, the Santee-Cooper, Edisto, Savannah, Ogeechee, and Altamaha rivers, and Lake Marion (King *et al.* 2014).

Subsequent analyses revealed that each of the three regions has a different pattern of sub-structuring. Within the Northeast group, two separate analyses (PCO and STRUCTURE) indicated a high degree of relatedness and possible

panmixia (*i.e.*, random mating of individuals) among the Penobscot, Kennebec, and Androscoggin rivers; whereas, the Saint John and Merrimack rivers appeared more differentiated from each other as well as from the other Gulf of Maine rivers (King *et al.* 2014). Pairwise comparisons at the population level showed that, within the Northeast region, estimates of genetic differentiation were greatest between the Saint John and Merrimack rivers ( $\Phi_{PT} = 0.100$ ,  $p < 0.0004$ ), the two most distant rivers within this region. Pairwise comparisons of the Saint John River to the remaining rivers within the Northeast region revealed lower but still statistically significant levels of genetic differentiation ( $\Phi_{PT} = 0.068$ – $0.077$ ; King *et al.* 2014). Relatively low levels of differentiation were observed in pairwise comparisons for all other rivers within the Northeast region ( $\Phi_{PT} = 0.013$ – $0.087$ ), half of which were not statistically significant (King *et al.* 2014). In comparison, within the Mid-Atlantic group, pairwise comparisons among rivers showed moderate levels of genetic differentiation among most river populations (average  $\Phi_{PT} = 0.077$ , range =  $0.018$ – $0.118$ ); whereas, estimates of population level genetic differentiation were very low among samples populations in the Southeast group (average  $\Phi_{PT} = 0.047$ , range =  $0.005$  to  $0.095$ ; King *et al.* 2014), suggesting a more genetically similar set of populations.

Theoretical estimates of gene flow (derived from  $\Phi_{PT}$  values) between the Saint John River and the other Northeast rivers ranged from 2.25 to 3.43 migrants per generation (King *et al.* 2014). Gene flow estimates for the Merrimack River were similarly low, ranging from 2.25 to 4.06 (King *et al.* 2014). In contrast, the effective number of migrants per generation estimated to occur between the remaining rivers within the Northeast region was much higher and ranged from 16.42 to 83.08 (King *et al.* 2014).

Overall, the analyses completed by King *et al.* (2014) indicate that differentiation among Northeast populations is less than that observed among the Mid-Atlantic populations and greater than that observed among Southeast populations. However, within the Northeast region, both the Saint John and Merrimack River sample populations are genetically distinct from the other sample populations. Although the estimates of gene flow suggest some connectivity between the Saint John and other rivers within the Northeast, the significantly different allele and haplotype frequencies shown consistently in the nDNA and mtDNA

studies provide indirect evidence that the Saint John River population is relatively reproductively isolated.

As highlighted in the DPS Policy, quantitative measures of morphological discontinuity or differentiation can serve as evidence of marked separation of populations. We examined whether the morphological data for shortnose sturgeon across its range provide evidence of marked separation of the Saint John River population. As noted previously, maximum adult size (length and weight) varies across the range, with the largest maximum sizes occurring in the Saint John River at the northernmost end of the range, and the smallest sizes occurring in rivers at the southern end of the range (Dadswell *et al.* 1984). The largest individual reported in the literature (122 cm FL, 23.6 kg) was captured in the Saint John River, although there is also a report of a specimen measuring 124.6 cm FL (M. Litvak, unpublished data, as cited in COSEWIC, In Press). Lengths of shortnose sturgeon captured in surveys of the Saint John River in 1974–1975 ranged from 60 to 120 cm FL ( $n=1,621$ ). The majority of these fish, however, were smaller than 100 cm FL (1,476 fish), and only six fish were longer than 111 cm FL (Dadswell 1979). To the south, in the Kennebec River, Maine shortnose sturgeon captured during 1980 and 1981 had lengths ranging from 58.5 to 103.0 cm FL, and averaging 80.8 cm FL ( $n=24$ ; Walsh *et al.* 2001). Smaller size ranges are reported for rivers in the southernmost portion of the range with some occasional captures of larger specimens. For example, adult shortnose sturgeon captured in the Altamaha River, Georgia, in 2010–2013 ranged from 57.4–83.0 cm FL and averaged 70.1 cm long (FL,  $n=40$ ; Peterson 2014), but a shortnose sturgeon measuring 104.5 cm FL and weighing 8.94 kg was captured in the Altamaha River in summer, 2004 (D. Peterson, UGA, unpubl. data). Overall, the attribute of size appears to display clinal variation, meaning there is a gradual change with geographic location (Huxley 1938). The fact that the Saint John River population segment, which lies at the northernmost end of the range, exhibits the largest sizes does not in itself constitute a morphological discontinuity. Given the apparent gradual nature of the variation in size with latitude, we find that there is no marked separation of the Saint John River population segment on the basis of a quantitative discontinuity in size. In addition to body size, other attributes such as snout length, head length, and mouth width can provide evidence of a morphological

discontinuity and were also considered. Walsh *et al.* (2001) examined six morphological and five meristic attributes for shortnose sturgeon in the Androscoggin, Kennebec, and Hudson rivers. All morphological features measured (*i.e.*, body length, snout length, head length, mouth width, and interorbital width) were largest for the Kennebec River fish and smallest for fish from the southern-most river in the study, the Hudson River (Walsh *et al.* 2001). Meristic features (*e.g.*, scute counts) were similar for the three rivers and were not related to fish size (Walsh *et al.* 2001). Overall, the degree of phenotypic differentiation of fish from the two rivers in Maine (Androscoggin and Kennebec), which share an estuary mouth, was very low, while a much greater degree of differentiation was observed for the fish from the Hudson River (Walsh *et al.* 2001). This result was congruent with results of corresponding mtDNA analyses, which indicated that the Hudson River had a much greater degree of genetic differentiation from, and much lower rate of gene flow with, the two rivers in Maine (Walsh *et al.* 2001). The results of this particular study suggest there could be clinal variation in these other phenotypic characteristics, similar to the pattern observed for body size. As far as we are aware, however, similar studies have not yet been conducted to examine the variation in additional sets of morphological attributes across the range of shortnose sturgeon and relative to the Saint John River population in particular. Therefore, there is no basis to conclude marked separation of the Saint John River population segment on the basis of morphological discontinuity.

In conclusion, although the currently available data do not show that the Saint John River shortnose sturgeon constitute a completely isolated or closed population, we find that available genetic data, evidence of site fidelity, and the likelihood of some degree of geographical isolation together constitute sufficient information to indicate that the Saint John River shortnose sturgeon are markedly separated from other populations of shortnose sturgeon. Thus, after considering the best available data and all public comments submitted in response to our initial petition finding, we conclude that the Saint John River population segment of shortnose sturgeon is “discrete.” We therefore proceeded to evaluate the best available data with respect to the second criterion of the DPS Policy, “significance.”

#### *Significance Criterion*

Under the DPS Policy, if a population segment is found to be discrete, then we proceed to the next step of evaluating its biological and ecological significance to the taxon to which it belongs. As we explained above, a population must be both “discrete” (the first prong of the DPS Policy) and “significant” (the second prong of the DPS Policy) to qualify for recognition as a DPS.

Consideration of significance may include, but is not limited to: (1) Persistence of the discrete population segment in an ecological setting unusual or unique for the taxon; (2) evidence that the loss of the discrete population segment would result in a significant gap in the range of a taxon; (3) evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historical range; and (4) evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics (61 FR 4722, February 7, 1996). These four factors are non-exclusive; other relevant factors may be considered in the “significance” analysis. Further, significance of the discrete population segment is not necessarily determined by existence of one of these classes of information standing alone. Rather, information analyzed under these and any other applicable considerations is evaluated relative to the biological and ecological importance of the discrete population to the taxon as a whole. Accordingly, all relevant and available biological and ecological information is analyzed to determine whether, because of its particular characteristics, the population is significant to the conservation of the taxon as a whole.

#### *Persistence in an Ecological Setting Unusual or Unique for the Taxon*

Shortnose sturgeon once occupied most major rivers systems along the Atlantic coast of North America (Kynard 1997). Although extirpated from some areas due mainly to overharvest, bycatch, pollution, and habitat degradation, shortnose sturgeon still occur in at least 25 rivers systems within their historical range (NMFS 1998). Throughout their current range, shortnose sturgeon occur in riverine, estuarine, and marine habitats; and, as adults, generally move seasonally between freshwater spawning habitat and downstream mesohaline and sometimes coastal marine areas in response to cues such as water temperature, flow, and salinity. Like

other species of sturgeon (*e.g.* *A. transmontanus* in the Columbia River, Oregon), shortnose sturgeon are also capable of adopting a fully freshwater existence, as is the case for the population of shortnose sturgeon above the Holyoke Dam in the Connecticut River and in Lake Marion, South Carolina. While each river system within the shortnose sturgeon’s range is similar in terms of its most basic features and functions, each river system differs to varying degrees in terms of its specific, physical and biological attributes, such as hydrologic regime, benthic substrates, water quality, and prey communities. A few examples are discussed briefly below.

The Saint John River begins in northern Maine, United States, travels through New Brunswick, Canada, and empties into the Bay of Fundy within the northeast Gulf of Maine. The river is approximately 673 km long, fed by numerous tributaries, and has a large tidal estuary and a basin area of over 55,000 km<sup>2</sup> (Kidd *et al.* 2011). According to the Nature Conservancy’s (TNC) ecoregion classification system, the Saint John River watershed lies within the New England-Acadian (terrestrial), Northeast United States and Southeast Canada Atlantic Drainages (freshwater), and the Gulf of Maine/Bay of Fundy (marine) ecoregions. The mean annual discharge is approximately 1,100 m<sup>3</sup>/s, dissolved oxygen levels average 8.5 to 11 mg/l, and benthic substrates downstream of the Mataquac Dam consist largely of shifting sands (Kidd *et al.* 2011). Due to the low slope of the lower reaches and the extreme tidal range of the Bay of Fundy, the head of the tide can extend about 140 km upstream from the river mouth (Kidd *et al.* 2011). During the shortnose sturgeon spring/summer spawning season, water temperatures range from about 10 to 15 °C; and within overwintering areas, water temperature range between 0 and 13 C (Dadswell 1979; Dadswell *et al.* 1984). Shortnose sturgeon in the Saint John River appear to move to deeper waters when surface water temperatures exceed 21 °C (Dadswell *et al.* 1984). Further to the south, but still within the same terrestrial, freshwater, and marine TNC ecoregions as the Saint John River, is the smaller Penobscot River system in Maine. This river is 175 km long (not including the West and South Branches), has a drainage basin of 22,265 km<sup>2</sup>, and an annual average discharge of about 342 m<sup>3</sup>/s (Lake *et al.* 2012; USGS 2015). Benthic substrates, consisting of bedrock, boulders, cobble and sand deposits are undergoing changes in response to the removal of

two dams—Great Works Dam at rkm 60 and Veazie Dam at rkm 48—within the past three years (FERC 2010; Cox *et al.* 2014). The Veazie Dam was located close to the head of the tide, and although conditions have since changed, Haefner (1967, as cited in Fernandes *et al.* 2010) stated that, during peak springtime flows, freshwater extends to rkm 17, and that the salt wedge intrudes as far as about rkm 42 when river discharges decrease in summer. Water temperatures in shortnose sturgeon overwintering areas in the Penobscot River range from about 0 °C to 13.3 °C, and the fish appear to move out of overwintering areas when water temperatures reach about 2.4 °C (Fernandes *et al.* 2010). Towards the southern end of the range and occurring within a very different set of ecoregions is the Altamaha River, which is formed by the confluence of the Ocmulgee and Oconee rivers in Georgia. One of the longest free-flowing systems on the Atlantic Coast, the Altamaha River is just over 220 km long, has a watershed area of about 37,300 km<sup>2</sup>, and flows mainly eastward before emptying into the Atlantic Ocean (TNC 2005). Tidal influence extends up to about rkm 40 (DeVries 2006). The average annual discharge is 381 m<sup>3</sup>/s, and benthic substrates consist mostly of sands with very few rocky outcrops (Heidt and Gilbert 1979; DeVries 2006). Water temperatures during the winter/spring spawning period have averaged about 10.5 °C (Heidt and Gilbert 1979), which is consistent with DeVries' (2006) observation that spawning runs appeared to commence when water temperatures reach 10.2 °C. When water temperatures exceed 27 °C, shortnose sturgeon typically move above the salt-fresh water interface and aggregate in deeper areas of the river (DeVries 2006); however, shortnose sturgeon have also been observed to use lower portions of the river throughout the summer, even when water temperatures averaged 34 °C (Heidt and Gilbert 1979; DeVries 2006).

Overall, the variation in habitat characteristics across the range of shortnose sturgeon indicates that there is no single type or typical river system. Despite a suite of existing threats, shortnose sturgeon continue to occupy many river systems across their historical range. The fact that the Saint John River lies at one end of the species' range, and among other attributes, experiences different temperature and flow regimes, does not mean that this particular river is unusual or unique given the variability in habitat conditions observed across the range.

Therefore, we conclude that the Saint John River is not an unusual or unique ecological setting when viewed against the range of the taxon as a whole. Furthermore, though not relied upon for our finding, we note that COSEWIC (In Press) recently concluded that shortnose sturgeon from other river systems would probably be able to survive in Canada.

#### *Significant Gap in the Range of the Taxon*

The second consideration under the DPS Policy in determining whether a population may be "significant" to its taxon is whether the "loss of the discrete population segment would result in a significant gap in the range of a taxon" (61 FR 4722, February 7, 1996). Shortnose sturgeon are distributed along the Atlantic coast of North America from the Minas Basin, Nova Scotia to the St. Johns River, Florida, representing a coastal range of roughly 3,700 km. The Saint John River, located at the northern end of the range, represents a small portion of the species' currently occupied geographic range. In addition, although the Saint John River is presumed to contain a relatively large population of shortnose sturgeon, that population is not considered the largest, and it represents one of at least 10 spawning populations (SSRT 2010). Furthermore, relatively recent field data indicate shortnose sturgeon make coastal migrations to a greater extent than previously thought (*e.g.*, Dionne *et al.* 2013) and are capable of making marine migrations of over 300 km (*e.g.*, between Penobscot and Merrimack rivers; M. Kieffer, USGS, pers. comm. 2010). Such data suggest the potential for recolonization of the Saint John River by shortnose sturgeon migrating from populations to the south. Further indirect evidence in support of this possibility comes from the existing genetic data, which indicate some level of gene flow among rivers in the Northeast, including the Saint John River (Wirgin *et al.* 2005; Wirgin *et al.* 2009; King *et al.* 2014). Thus, in light of the potential for recolonization and the fact that the Saint John River population of shortnose sturgeon does not constitute a substantial proportion of the species' range, we conclude that the loss of the Saint John River would not constitute a significant gap in the range of the species.

#### *Only Natural Occurrence of the Taxon*

Under the DPS Policy, a discrete population segment that represents the "only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population

outside its historical range" may be significant to the taxon as whole (61 FR 4722, February 7, 1996). This consideration is not relevant in this particular case, because shortnose sturgeon are present in many river systems throughout their historical range (SSRT 2010).

#### *Genetic Characteristics*

As stated in the DPS Policy, in assessing the "significance" of a "discrete" population, we consider whether the discrete population segment differs markedly from other populations of the species in its genetic characteristics (61 FR 4722, February 7, 1996). Therefore, we examined the available data to determine whether the Saint John River shortnose sturgeon differ markedly in their genetic characteristics when compared to other populations. In conducting this evaluation under the second criterion of the DPS policy, we looked beyond whether the genetic data allow for discrimination of the Saint John population segment from other populations (a topic of evaluation in connection with the first criterion of "discreteness"), and instead focused on whether the data indicate marked genetic differences that appear to be significant to the taxon as a whole. In this sense, we give independent meaning to the "genetic discontinuity" of the discreteness criterion of the DPS Policy and the "markedly differing genetic characteristics" of the significance criterion.

Genetic analyses indicate fairly moderate to high levels of genetic diversity of shortnose sturgeon in most river systems across the geographic range (Grunwald *et al.* 2002, Quattro *et al.* 2002; Wirgin *et al.* 2009). Based on the 11 nDNA loci examined in samples from 17 locations, King *et al.* (2014) reported that the number of observed alleles (*i.e.*, versions of a gene at a particular locus; here with overall frequencies >1%) ranged from a low of 55 in the Cape Fear River (n= 3 fish) to a high of 152 in the Hudson River (n= 45 fish); 118 alleles were observed in the Saint John River sample (n=25 fish). Estimated heterozygosity was not reported by river sample, but King *et al.* (2014) noted that it was lowest for the southern rivers relative to the mid-Atlantic and northern river samples. Wirgin *et al.* (2009) reported that haplotypic diversity ranged from 0.500 (Santee River, n=4) to 0.862 (Altamaha River, n= 69) across 15 sample populations, with the Saint John River population having a haplotype diversity index of 0.696 (n=42). The number of individual haplotypes observed in any



one river sample ranged from two (Santee River,  $n=4$ ) to 13 (Winyah Bay,  $n=46$ ), with eight haplotypes observed in the Saint John River sample ( $n=42$ , Wirgin *et al.* 2009). The level of genetic diversity based on the mtDNA was not correlated with population size, and there was also no evidence of population bottlenecks, which may be due to historical recency of most population declines (over past ~100 years, Grunwald *et al.* 2002; Wirgin *et al.* 2009). Overall, the level of genetic diversity observed for the Saint John River population segment is not unusual relative to that observed in the taxon as a whole. However, Grunwald *et al.* (2002) noted that the lack of reduced haplotypic diversity within the northern sample rivers contrasts with findings for other anadromous fishes from previously glaciated rivers. Grunwald *et al.* (2002) hypothesized the high degree of haplotypic diversity and large number of unique haplotypes in the previously glaciated northern region (*i.e.*, Hudson River and northward) may be the result of a northern population having survived in one or more northern refugia.

As discussed previously, at a regional scale, most of the mtDNA haplotypes observed are shared across multiple, adjacent rivers sampled; however, very little sharing of haplotypes has been documented between the northern and southern portions of the range (Quattro *et al.* 2002; Grunwald *et al.* 2002; Wirgin *et al.* 2009). In the analysis conducted by Wirgin *et al.* (2009), the Saint John River sample had one private haplotype (in 1 of 42 fish) and shared the remaining 7 haplotypes with multiple rivers. Of the seven shared haplotypes, two were each shared with two other river systems, including the Hudson and Connecticut rivers, and the remaining five haplotypes were shared across three to six other rivers within the northeast and mid-Atlantic portions of the range (Wirgin *et al.* 2009). In an earlier study by Quattro *et al.* (2002) in which control region mtDNA was sequenced for 211 shortnose sturgeon collected from five southeastern U.S. rivers and the Saint John River, one haplotype was observed in all river samples. This shared haplotype occurred in 1 of 13 fish (7.7%) sampled from the Saint John River and 1 of 5 fish (20%) sampled from Winyah Bay; the remaining river samples contained this haplotype at higher frequencies (36%–79%, Quattro *et al.* 2002).

While the shortnose sturgeon from the Saint John River have a fairly high degree of genetic diversity and shared haplotypes with other rivers, they can be statistically differentiated from other

river samples based on haplotype frequencies and nDNA distance metrics (Wirgin *et al.* 2009; King *et al.* 2014). However, the same is also true for the majority of rivers across the range of the species. For example, using genetic distances ( $\Phi_{PT}$ ), King *et al.* (2014) detected significant differences in all pairwise comparisons except for three rivers in the northeast (Penobscot, Androscoggin, and Kennebec rivers) and three rivers in the southeast (Edisto, Savannah, and Ogeechee rivers). Similarly, significant differences in haplotype frequencies have been reported for most river populations sampled. In Chi-squared analyses, Grunwald *et al.* (2002) reported significant differences for all but 4 of 82 pairwise comparisons of mtDNA nucleotide substitution haplotype frequencies across 10 sample sets (two of which were from different sections of the Connecticut River), and Wirgin *et al.* (2009) reported significant differences for all but 9 of 91 pairwise comparisons of mtDNA haplotype frequencies across 13 river populations.

The magnitude of these genetic differences between individual river systems varies across the range of the species and indicates a hierarchical pattern of differentiation. For example, the mtDNA data reveal a deep divergence between rivers in the northern portion of the range from rivers in the southern portion of the range. Of the 29 haplotypes observed by Grunwald *et al.* (2002), 11 (37.9%) were restricted to northern systems, 13 (44.8%) were restricted to the more southern systems, and only 5 (17.2%) slightly overlapped the two regions. In the later and larger study by Wirgin *et al.* (2009), the observed haplotypes again clustered into regional groupings: 10 of 38 observed haplotypes (26.3%) only occurred in systems north of the Hudson River, 16 of 38 (42.1%) only occurred in systems south of the Chesapeake Bay, and just 5 of 38 (13.2%) haplotypes overlapped in the mid-Atlantic region. The limited sharing of haplotypes between the north and south regions is consistent with strong female homing fidelity and limited gene flow between these regions. The break in shared haplotypes corresponds with the historical division of the species due to Pleistocene glaciation, which Grunwald *et al.* (2002) stated was probably the most significant event affecting population structure and patterns of mtDNA diversity in shortnose sturgeon.

The recent nDNA analyses of King *et al.* (2014) also indicate an unambiguous differentiation of sample populations into one of three major geographic

groupings—Northeast, Mid-Atlantic, or Southeast. When all 17 sample populations were pooled by these three geographic regions, correct assignment to each region was 99.1% for the Northeast and 100% (*i.e.*, zero mis-assigned fish) for the remaining two regions (King *et al.* 2014). Of the 133 fish included for the Northeast group, one was mis-assigned to the Mid-Atlantic. The estimates of effective migrants per generation (based on  $\Phi_{PT}$ ) are consistent with the regional zones of genetic discontinuity among Northeast, Mid-Atlantic, and Southeast river systems. The average migrants per generation between regions ranged from less than one migrant (*i.e.*, 0.89) between Northeast and Southeast to nearly two migrants (*i.e.*, 1.89) between Northeast and Mid-Atlantic. In contrast, the range of estimated migrants per generation within regions was 2.25–83.08 for the Northeast, 1.87–13.64 for the Mid-Atlantic, and 2.38–49.75 for the Southeast (King *et al.* 2014). The estimated migrants per generation between the Saint John River in particular and all other rivers within the Northeast ranged from 2.25–3.43 (King *et al.* 2014). Taken together, these data indicate that the degree of genetic differentiation between the Saint John River and the rivers within the Gulf of Maine is relatively small or “shallow”, especially relative to the deeper divergence observed among the regional groupings of river populations. A possible explanation for the relatively low level of differentiation within the Northeast is that the those populations are relatively young in a geologic sense due to recent glaciations compared to populations in the more southern part of the range (SSRT 2010).

In conclusion, given the patterns of genetic diversity, shared haplotypes, and relative magnitudes of genetic divergence at the river drainage versus regional scale, we find there is insufficient evidence that the Saint John River population of shortnose sturgeon differs markedly in its genetic characteristics relative to the taxon as a whole so as to meet the test for “significance” on this basis. While the Saint John River population segment can be genetically distinguished from other river populations, available genetic evidence places it into a larger evolutionarily meaningful unit, along with several other river populations sampled. The degree of differentiation among the three larger regional groups is more marked than the differences observed among populations from the Saint John and other nearest rivers, suggesting that the Saint John River



population's differentiation is not "significant" in the context of the whole species. Gene flow estimates are also consistent with the observed deeper zones of divergence detected at the regional scale. Thus, we conclude that these data do not support delineation of the Saint John River population segment as "significant." In so interpreting the available genetic data, we are mindful of the Congressional guidance to use the DPS designation sparingly.

#### **DPS Conclusion and Petition Finding**

We conclude that the Saint John River population of shortnose sturgeon is "discrete" based on evidence that it is a relatively closed and somewhat geographically isolated population segment. It thus satisfies the first prong of the DPS policy. However, we also find that the Saint John River population segment is not "significant" to the taxon as a whole. It thus fails to satisfy the second prong of the DPS

Policy. As such, based on the best available data, we conclude that the Saint John River population of shortnose sturgeon does not constitute a DPS and, thus, does not qualify as a "species" under the ESA. Therefore, we deny the petition to consider this DPS for delisting. Our denial of the petition on this ground does not imply any finding as to how we should proceed if the situation were otherwise, *i.e.*, where a population is found instead to meet the criteria to be a DPS. Even if the population had met both criteria of the DPS Policy, and even if the population were also found to have a status that differed from the listed entity, it would not necessarily be appropriate to propose modifications to the current listing, in light of the unsettled legal issues surrounding such revisions. Nor do we resolve here what steps would need to be followed to propose revisions to the species' listing if the facts had been otherwise; such an inquiry would

be hypothetical in this case. It is clear that because the petition at issue here sought identification of a DPS, and because the population at issue is not a DPS, this particular petition must be denied. As this is a final action, we do not solicit comments on it.

#### **References Cited**

A complete list of references is available upon request to the Office of Protected Resources (see **ADDRESSES**).

#### **Authority**

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: October 20, 2015.

**Samuel D. Rauch III,**

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

[FR Doc. 2015-27148 Filed 10-23-15; 8:45 am]

**BILLING CODE 3510-22-P**

# Notices

Federal Register

Vol. 80, No. 206

Monday, October 26, 2015

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### Submission for OMB Review; Comment Request

October 20, 2015.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by November 25, 2015 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725-17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: [OIRA\\_Submission@OMB.EOP.GOV](mailto:OIRA_Submission@OMB.EOP.GOV) or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

#### Animal and Plant Health Inspection Service

*Title:* Special Need Request Under the Plant Protection Act.

*OMB Control Number:* 0579–0291.

*Summary of Collection:* The Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture, which administers regulations to implement the PPA. Regulations governing the interstate movement of plants, plant products, and other articles are contained in 7 CFR part 301, “Domestic Quarantine Notices.” These regulations allow States or political subdivisions of States to request approval from APHIS to impose prohibitions or restrictions on the movement in interstate commerce of specific articles that pose a plant health risk that are in addition to the prohibitions and restrictions imposed by APHIS.

*Need and Use of the Information:*

APHIS believes that specific information—such as a pest data detection survey with a pest risk analysis that shows that a pest is not present in a State, or if already present, the current distribution in the State, and that the pest would harm or injure the environment and/or agricultural resources of the State or political subdivision—is needed and would be considered along with more general information available to APHIS for the Administrator to be able to determine whether to grant or deny a request for a special need exemption. The administrator's determination would be based upon his or her review of the information submitted by the State or

political subdivision in support of its request and would take into account any comments received.

*Description of Respondents:* State, Local or Tribal Government.

*Number of Respondents:* 1.

*Frequency of Responses:* Reporting: On occasion.

*Total Burden Hours:* 160.

**Ruth Brown,**

*Departmental Information Collection Clearance Officer.*

[FR Doc. 2015–27093 Filed 10–23–15; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### National Agricultural Statistics Service

#### Notice of Intent To Request To Conduct a New Information Collection

**AGENCY:** National Agricultural Statistics Service, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to seek approval to conduct a new information collection to gather data related to the production and marketing of foods directly from farm producers to consumers or retailers. In addition NASS will collect some whole-farm data to be used to classify and group operations for summarizing and publication of results.

**DATES:** Comments on this notice must be received by December 28, 2015 to be assured of consideration.

**ADDRESSES:** You may submit comments, identified by docket number 0535–NEW, by any of the following methods:

- *Email:* [ombofficer@nass.usda.gov](mailto:ombofficer@nass.usda.gov).

Include docket number above in the subject line of the message.

- *E-fax:* (855) 838–6382.

- *Mail:* Mail any paper, disk, or CD-ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.

- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building,

1400 Independence Avenue SW.,  
Washington, DC 20250–2024.

**FOR FURTHER INFORMATION CONTACT:** R. Renee Picanso, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–2707. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at [ombofficer@nass.usda.gov](mailto:ombofficer@nass.usda.gov).

**SUPPLEMENTARY INFORMATION:**

*Title:* Local Foods Survey.

*OMB Control Number:* 0535—NEW.

*Type of Request:* Intent to seek approval to conduct a new information collection for a period of three years.

*Abstract:* Interest is growing in support of local agricultural economies through the purchase of foods from sources that are geographically close to the consuming areas, via channels that are direct from farm to consumer or at most one step removed. Significant policy support for local food systems occurred with the institution of the USDA Know Your Farmer, Know Your Food Initiative (KYF2) in September 2009. The KYF2 Initiative was designed to eliminate organizational barriers to improve coordination and availability of resources for the promotion of local food systems. This initiative is in response to the perceived consumer and producer interests. Many community and farm advocacy groups are requesting changes in the next major agricultural program legislation (the Farm Bill) that will directly target local foods producers, consumers, and markets. Despite the emphasis of policy makers, there are currently no available data sources that provide representative and reliable national estimates of local food production.

As a direct response to this interest in local foods, NASS included a question in the 2012 Census of Agriculture to capture data needed to benchmark the size of the intermediated local foods market. Contingent upon the availability of funding, the Local Foods Survey will be a Census follow-on survey. As a follow-on survey, it will be sampled from respondents to the 2012 Census of Agriculture who reported product sales directly to consumers or to retail outlets that in turn sell directly to consumers. Response to this survey will be voluntary.

*Authority:* The data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict

confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501, *et seq.*), and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, “Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),” **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average 50 minutes per response. NASS plans to mail out publicity materials with the questionnaires to inform producers of the importance of this survey. NASS will also use multiple mailings, followed up with phone and limited personal enumeration to increase response rates and to minimize data collection costs.

*Respondents:* Farmers and Ranchers.

*Estimated Number of Respondents:* 28,000.

*Estimated Total Annual Burden on Respondents:* 21,000 hours.

*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 will 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 the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological, or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, October 16, 2015.

**R. Renee Picanso,**

*Associate Administrator.*

[FR Doc. 2015–27139 Filed 10–23–15; 8:45 am]

**BILLING CODE 3410–20–P**

## COMMISSION ON CIVIL RIGHTS

### Public Meeting of the Mississippi Advisory Committee; Advisory Memorandum Regarding Civil Rights Concerns Relating to Distribution of Federal Child Care Subsidies in Mississippi

**AGENCY:** U.S. Commission on Civil Rights.

**ACTION:** Announcement of meeting.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Mississippi Advisory Committee (Committee) will hold a meeting on Thursday, November 19, 2015, at 2:00 p.m. CST for the purpose of discussing and voting on an advisory memorandum on civil rights concerns relating to potential disparities in the distribution of federal child care subsidies in Mississippi on the basis of race or color. The committee previously gathered testimony on this topic on April 29, 2015, and May 13, 2015.

Members of the public may listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 888–505–4369, conference ID: 4796911. Any interested member of the public may call this number and listen to the meeting. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines according to their wireless plan, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Member of the public are also invited and welcomed to make statements at the end of the conference call. In addition, members of the public may submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or

emailed to Administrative Assistant, Corrine Sanders at [csanders@usccr.gov](mailto:csanders@usccr.gov). Persons who desire additional information may contact the Regional Programs Unit at (312) 353-8311.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at <http://facadatabase.gov/committee/meetings.aspx?cid=257> and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, <http://www.usccr.gov>, or may contact the Regional Programs Unit at the above email or street address.

### Agenda

Welcome and Introductions

Susan Glisson, Chair

Discussion and Vote on Childcare

Subsidy Advisory Memorandum

Mississippi Advisory Committee

Open Comment

Adjournment

**DATES:** The meeting will be held on Thursday, November 19, 2015, at 2:00 p.m. CST. Public Call Information: Dial: 888-505-4369, Conference ID: 4796911.

**FOR FURTHER INFORMATION CONTACT:** Melissa Wojnaroski, DFO, at 312-353-8311 or [mwojnaroski@usccr.gov](mailto:mwojnaroski@usccr.gov).

Dated October 21, 2015.

**David Mussatt,**

Chief, Regional Programs Unit.

[FR Doc. 2015-27112 Filed 10-23-15; 8:45 am]

**BILLING CODE 6335-01-P**

## COMMISSION ON CIVIL RIGHTS

### Notice of Public Meeting of the Oklahoma Advisory Committee To Discuss Findings and Recommendations Resulting From Its Inquiry Into the Civil Rights Impact of School Disciplinary Policies That May Contribute to High Rates of Juvenile Incarceration in Oklahoma

**AGENCY:** U.S. Commission on Civil Rights.

**ACTION:** Announcement of meeting.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Oklahoma Advisory Committee (Committee) will hold a meeting on Monday, November 9, 2015, from 1:00-2:30 p.m. CST for the purpose of

discussing and findings and recommendations related to its inquiry regarding the civil rights impact of the "school to prison pipeline" in Oklahoma.

Members of the public may listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 888-539-3678, conference ID: 6512744. Any interested member of the public may call this number and listen to the meeting. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines according to their wireless plan, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1-800-977-8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also invited and welcomed to make statements at the end of the conference call. In addition, members of the public may submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353-8324, or emailed to Administrative Assistant, Corrine Sanders at [csanders@usccr.gov](mailto:csanders@usccr.gov). Persons who desire additional information may contact the Regional Programs Unit at (312) 353-8311.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at: <https://database.faca.gov/committee/meetings.aspx?cid=269> and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, <http://www.usccr.gov>, or may contact the Regional Programs Unit at the above email or street address.

### Agenda

Welcome and Roll Call

Discussion of findings and recommendations regarding "Civil Rights and the School to Prison Pipeline in Oklahoma"

Open Comment

Adjournment

**DATES:** The meeting will be held on Monday, November 9, 2015, from 1:00-2:30 p.m. CST.

### Public Call Information

Dial: 888-539-3678.

Conference ID: 6512744.

**FOR FURTHER INFORMATION CONTACT:** Melissa Wojnaroski, DFO, at 312-353-8311 or [mwojnaroski@usccr.gov](mailto:mwojnaroski@usccr.gov).

Dated October 21, 2015.

**David Mussatt,**

Chief, Regional Programs Unit.

[FR Doc. 2015-27113 Filed 10-23-15; 8:45 am]

**BILLING CODE 6335-01-P**

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

**Agency:** Bureau of Economic Analysis (BEA), Department of Commerce.

**Title:** Quarterly Survey of Transactions in Selected Services and Intellectual Property with Foreign Persons.

**OMB Control Number:** 0608-0067.

**Form Number:** BE-125.

**Type of Request:** Regular submission.

**Number of Responses:** 8,800 annually (2,200 filed each quarter; 1,700 reporting mandatory data, and 500 that would file other responses).

**Average Hours per Response:** 18 hours is the average for those reporting data and 1 hour is the average for those not reporting data or providing voluntary responses, but hours may vary considerably among respondents because of differences in company size and complexity.

**Estimated Total Annual Burden Hours:** 124,400.

**Needs and Uses:** The Quarterly Survey of Transactions in Selected Services and Intellectual Property with Foreign Persons (BE-125) is a survey that collects data from U.S. persons that engage in covered transactions with foreign persons in selected services or intellectual property. A U.S. person must report if sales of covered services or intellectual property to foreign

persons exceeded \$6 million for the previous fiscal year, or if sales are expected to exceed that amount during the current fiscal year, or if purchases of covered services or intellectual property from foreign persons exceeded \$4 million for the previous fiscal year, or they are expected to exceed that amount during the current fiscal year.

The data are needed to monitor U.S. trade in services, to analyze the impact on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the services component of the U.S. international transactions accounts and national income and product accounts.

The Bureau of Economic Analysis (BEA) is proposing the following additions and modifications to the current BE-125 survey to increase the quality and usefulness of BEA's published statistics on trade in services:

(1) Two new schedules, Schedules D and E, will be added to collect additional information related to intellectual property and merchanting services. Schedule D is to be completed by a U.S. person who engages in intellectual property transactions with foreign persons. Schedule E is to be completed by a U.S. person who engages in merchanting services transactions with foreign persons.

(2) Several services categories that are currently collected as part of "other selected services" will be collected separately. These services include audiovisual services, artistic-related services, health services, heritage and recreational services, and other personal services.

(3) "Maintenance services" will be collected separately from "installation, alteration, and training services."

BEA estimates the proposed changes will increase the average number of hours per response from 16 hours to 18 hours for those reporting data. The reporting thresholds of the current BE-125 survey will be retained. The effort to keep current reporting thresholds unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

**Affected Public:** Businesses or other for-profit organizations.

**Frequency:** Quarterly.

**Respondent's Obligation:** Mandatory.

This information collection request may be viewed at [www.reginfo.gov](http://www.reginfo.gov). Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov) or fax to (202) 395-5806.

Dated: October 21, 2015.

**Sheleen Dumas,**

*PRA Departmental Lead, Office of the Chief Information Officer.*

[FR Doc. 2015-27144 Filed 10-23-15; 8:45 am]

**BILLING CODE 3510-06-P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-570-890]

#### Wooden Bedroom Furniture From the People's Republic of China: Partial Rescission of Antidumping Duty Administrative Review

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** On March 2, 2015, the Department of Commerce (Department) published the notice of initiation of an administrative review of the antidumping duty order on wooden bedroom furniture from the People's Republic of China (PRC).<sup>1</sup> The review covers 127 companies. Based on timely withdrawals of all review requests for certain companies, we are now rescinding the administrative review with respect to 109 companies.

**DATES:** *Effective Date:* October 26, 2015.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Pedersen or Patrick O'Connor, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482-2769 or (202) 482-0989, respectively.

#### Background

On January 2, 2015, the Department published a notice of opportunity to request an administrative review of the antidumping duty order on wooden bedroom furniture from the PRC.<sup>2</sup> In

<sup>1</sup> See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 80 FR 11166 (March 2, 2015) (*Initiation Notice*).

<sup>2</sup> See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 80 FR 27 (January 2, 2015).

January 2015, the Department received multiple timely requests to conduct an administrative review of the antidumping duty order on wooden bedroom furniture from the PRC. On March 2, 2015, in accordance with section 751(a) of Tariff Act of 1930, as amended (the Act), the Department published in the **Federal Register** a notice of the initiation of an administrative review of that order.<sup>3</sup> The administrative review was initiated with respect to 127 companies, and covers the period from January 1, 2014, through December 31, 2014. While a number of companies remain under review, the requesting parties have timely withdrawn all review requests for certain companies, as discussed below.

#### Rescission of Review, in Part

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if a party that requested the review withdraws its request within 90 days of the date of publication of the notice of initiation of the requested review. All requesting parties withdrew their respective requests for an administrative review of the companies listed in the Appendix within 90 days of the date of publication of *Initiation Notice*. Accordingly, the Department is rescinding this review, in part, with respect to these companies, in accordance with 19 CFR 351.213(d)(1).<sup>4</sup>

#### Assessment

The Department will instruct U.S. Customs and Border Protection ("CBP") to assess antidumping duties on all appropriate entries. For the companies for which this review is rescinded, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice.

<sup>3</sup> See *Initiation Notice*.

<sup>4</sup> See Appendix. As stated in *Change in Practice in NME Reviews*, the Department will no longer consider the non-market economy ("NME") entity as an exporter conditionally subject to administrative reviews. See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963 (November 4, 2013) ("*Change in Practice in NME Reviews*").

**Notification to Importers**

This notice serves as the only reminder to importers whose entries will be liquidated as a result of this rescission notice, of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's assumption that the reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

**Notification Regarding Administrative Protective Orders**

This notice also serves as a reminder to parties subject to administrative protective orders ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under an APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: October 15, 2015.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

**Appendix**

- Art Heritage International, Ltd., Super Art Furniture Co., Ltd., Artwork Metal & Plastic Co., Ltd., Jibson Industries Ltd., Always Loyal International
- Balanza Co., Ltd.
- Best King International Ltd.
- Billionworth Enterprises Ltd.
- BNBM Co. Ltd. (aka Beijing New Materials Co., Ltd.)
- Brittomart Inc.
- C.F. Kent Co., Inc.
- C.F. Kent Hospitality, Inc.
- Changshu Htc Import & Export Co., Ltd.
- Cheng Meng Furniture (PTE) Ltd., Cheng Meng Decoration & Furniture (Suzhou) Co., Ltd.
- Chuan Fa Furniture Factory
- Classic Furniture Global Co., Ltd.
- Dalian Guangming Furniture Co., Ltd.
- Dalian Huafeng Furniture Co., Ltd.
- Dalian Huafeng Furniture Group Co., Ltd.
- Decca Furniture Ltd.
- Der Cheng Furniture Co., Ltd.
- Der Cheng Wooden Works Of Factory
- Dongguan Bon Ten Furniture Co., Ltd.
- Dongguan Dong He Furniture Co., Ltd.
- Dongguan Fortune Furniture Ltd.
- Dongguan Grand Style Furniture Co., Ltd.
- Dongguan Kingstone Furniture Co., Ltd., Kingstone Furniture Co., Ltd.
- Dongguan Lung Dong Furniture Co., Ltd.
- Dongguan Mingsheng Furniture Co., Ltd.
- Dongguan Mu Si Furniture Co., Ltd.
- Dongguan Nova Furniture Co., Ltd.
- Dongguan Sunrise Furniture Co., Ltd., Taicang Sunrise Wood Industry Co., Ltd., Taicang Fairmount Designs Furniture Co., Ltd., Meizhou Sunrise Furniture Co., Ltd.
- Dongguan Sunshine Furniture Co., Ltd.
- Dongguan Yujia Furniture Co., Ltd.
- Dongying Huanghekou Furniture Industry Co., Ltd.
- Dorbest Ltd., Rui Feng Woodwork Co., Ltd. Aka Rui Feng Woodwork (Dongguan) Co., Ltd., Rui Feng Lumber Development Co., Ltd. Aka Rui Feng Lumber Development (Shenzhen) Co., Ltd.
- Dream Rooms Furniture (Shanghai) Co., Ltd.
- Fairmont Designs
- Fine Furniture (Shanghai) Ltd.
- Fleetwood Fine Furniture LP
- Fortune Furniture Ltd.
- Fortune Glory Industrial Ltd. (H.K. Ltd.), Tradewinds Furniture Ltd.
- Fujian Lianfu Forestry Co., Ltd. aka Fujian Wonder Pacific Inc.
- Fuzhou Huan Mei Furniture Co., Ltd.
- Guangdong New Four Seas Furniture Manufacturing Ltd.
- Guangzhou Lucky Furniture Co., Ltd.
- Guangzhou Maria Yee Furnishings Ltd., Pyla HK Ltd., Maria Yee, Inc.
- Hainan Jong Bao Lumber Co., Ltd.
- Haining Kareno Furniture Co., Ltd.
- Hang Hai Woodcraft's Art Factory
- Hong Kong Da Zhi Furniture Co., Ltd.
- Huasen Furniture Co., Ltd.
- Hung Fai Wood Products Factory Ltd.
- Jasonwood Industrial Co., Ltd. S.A.
- Jiangmen Kinwai Furniture Decoration Co., Ltd.
- Jiangmen Kinwai International Furniture Co., Ltd.
- Jiangsu Dare Furniture Co., Ltd.
- Jiangsu Xiangsheng Bedtime Furniture Co., Ltd.
- Jiangsu Yuexing Furniture Group Co., Ltd.
- Jibbon Enterprise Co., Ltd.
- Jiedong Lehouse Furniture Co., Ltd.
- King Rich International, Ltd.
- King's Group Furniture (ENT) Co., Ltd.
- King's Way Furniture Industries Co., Ltd.
- Kingsyear Ltd.
- Kunshan Summit Furniture Co., Ltd.
- Leefu Wood (Dongguan) Co., Ltd.
- Nanhai Jiantai Woodwork Co., Ltd., Fortune Glory Industrial Ltd. (H.K. Ltd.)
- Nantong Wangzhuang Furniture
- Nantong Yangzi Furniture Co., Ltd.
- Nathan International Ltd., Nathan Rattan Factory
- Passwell Corporation, Pleasant Wave Ltd.
- Perfect Line Furniture Co., Ltd.
- Putian Jinggong Furniture Co., Ltd.
- Qingdao Beiyuan Shengli Furniture Co., Ltd., Qingdao Beiyuan Industry Trading Co., Ltd.
- Qingdao Liangmu Co., Ltd.
- Qingdao Shengchang Wooden Co., Ltd.
- Restonic (Dongguan) Furniture Ltd., Restonic Far East (Samoa) Ltd.
- Sen Yeong International Co., Ltd., Sheh Hau International Trading Ltd.
- Shanghai Chengguan Import & Export, Ltd.
- Shanghai Jiangfeng Furniture
- Shanghai Sinofound Imp. & Exp. Co., Ltd.
- Shanghai Sunrise Furniture Co., Ltd.
- Shenzhen Forest Furniture Co., Ltd.
- Shenzhen Jiifa High Grade Furniture Co., Ltd., Golden Lion International Trading Ltd.
- Shenzhen New Fudu Furniture Co., Ltd.
- Shenzhen Wonderful Furniture Co., Ltd.
- Shenzhen Xingli Furniture Co., Ltd.
- Shing Mark Enterprise Co., Ltd., Carven Industries Limited (BVI), Carven Industries Limited (HK), Dongguan Zhenxin Furniture Co., Ltd., Dongguan Yongpeng Furniture Co., Ltd.
- Songgang Jasonwood Furniture Factory
- Starwood Industries Ltd.
- Strongson Furniture (Shenzhen) Co., Ltd., Strongson Furniture Co., Ltd., Strongson (Hk) Co.
- Sunforce Furniture (Hui-Yang) Co., Ltd., Sun Fung Wooden Factory, Sun Fung Co., Shin Feng Furniture Co., Ltd., Stupendous International Co., Ltd.
- Superwood Co., Ltd., Lianjiang Zongyu Art Products Co., Ltd.
- Teamway Furniture (Dong Guan) Co., Ltd.
- Techniwood Industries Ltd., Ningbo Furniture Industries Ltd., Ningbo Hengrun Furniture Co., Ltd.
- Tianjin Phu Shing Woodwork Enterprise Co., Ltd.
- Tube-Smith Enterprise (Haimen) Co., Ltd.
- Tube-Smith Enterprise (Zhangzhou) Co., Ltd.
- U-Rich Furniture (Zhangzhou) Co., Ltd., U-Rich Furniture Ltd.
- Xiamen Yongquan Sci-Tech Development Co., Ltd.
- Xilinmen Group Co., Ltd.
- Yichun Guangming Furniture Co., Ltd.
- Yihua Timber Industry Co., Ltd., Guangdong Yihua Timber Industry Co., Ltd.
- Zhang Zhou Sanlong Wood Product Co., Ltd.
- Zhangjiagang Daye Hotel Furniture Co., Ltd.
- Zhangjiang Sunwin Arts & Crafts Co., Ltd.
- Zhangzhou Guohui Industrial & Trade Co., Ltd.
- Zhong Shan Fullwin Furniture Co., Ltd.
- Zhong Shun Wood Art Co.
- Zhongshan Fookiyk Furniture Co., Ltd.
- Zhongshan Golden King Furniture Industrial Co., Ltd.
- Zhoushan For-Strong Wood Co., Ltd.

[FR Doc. 2015-27157 Filed 10-23-15; 8:45 am]

**BILLING CODE 3510-DS-P**

## DEPARTMENT OF COMMERCE

## International Trade Administration

[A-570-970]

**Multilayered Wood Flooring From the People's Republic of China: Initiation of Antidumping Duty New Shipper Review; 2013-2014**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce ("Department") is initiating a new shipper review of the antidumping duty order on multilayered wood flooring from the People's Republic of China ("PRC"). The period of review ("POR") for the new shipper review is December 1, 2013, through November 30, 2014.<sup>1</sup>

**DATES:** *Effective Date:* October 26, 2015.

**FOR FURTHER INFORMATION CONTACT:**

Maisha Cryor or Robert Bolling, AD/CVD Operations, Office 4, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: 202-482-5831 or 202-482-3434, respectively.

**SUPPLEMENTARY INFORMATION:****Background**

The Department published the antidumping duty order on multilayered wood flooring from the PRC on December 8, 2011.<sup>2</sup> On December 19, 2014, the Department received a timely new shipper review request from Qingdao Barry Flooring Co., Ltd ("Qingdao Barry"),<sup>3</sup> in accordance with

<sup>1</sup> Pursuant to 19 CFR 351.214(g)(1)(i)(A), the POR for a new shipper review initiated in the month immediately following the anniversary month is the twelve-month period immediately preceding the anniversary month. However, this review is being initiated in accordance with an order entered by the U.S. Court of International Trade ("CIT") on October 14, 2015. In that order, the CIT authorized the Department to initiate and conduct this new shipper review based upon Qingdao Barry's December 19, 2014 review request. Accordingly, we have used that submission to determine the POR. See 19 CFR 351.214(d)(1) (providing for initiation of new shipper reviews in the calendar month following the anniversary month if the request is made in the 6-month period ending in the anniversary month); 19 CFR 351.214(g)(1)(i)(A) (setting the POR for new shipper reviews initiated in the month following the anniversary month).

<sup>2</sup> See *Multilayered Wood Flooring from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order*, 76 FR 76690 (December 8, 2011) ("Order"), as amended *Multilayered Wood Flooring from the People's Republic of China: Amended Antidumping and Countervailing Duty Orders*, 77 FR 5484 (February 3, 2012).

<sup>3</sup> See Letter from Qingdao Barry to the Secretary of Commerce "Multilayered Wood Flooring from China: Request for New Shipper Review," dated December 19, 2014 ("Initiation Request").

section 751(a)(2)(B)(i) of the Tariff Act of 1930, as amended ("the Act"), and 19 CFR 351.214(c).

In its submission, Qingdao Barry certified that it is both the producer and exporter of the subject merchandise upon which its respective review request was based.<sup>4</sup> Pursuant to section 751(a)(2)(B)(i)(I) of the Act and 19 CFR 351.214(b)(2)(i), Qingdao Barry certified that it did not export multilayered wood flooring to the United States during the period of investigation ("POI").<sup>5</sup> In addition, pursuant to section 751(a)(2)(B)(i)(II) of the Act and 19 CFR 351.214(b)(2)(iii)(A), Qingdao Barry certified that, since the initiation of the investigation, it has never been affiliated with any producer or exporter that exported multilayered wood flooring to the United States during the POI, including those not individually examined during the investigation.<sup>6</sup> As required by 19 CFR 351.214(b)(2)(iii)(B), Qingdao Barry also certified that its export activities are not controlled by the central government of the PRC.<sup>7</sup>

In addition to the certifications described above, pursuant to 19 CFR 351.214(b)(2)(iv), Qingdao Barry submitted documentation establishing the following: (1) The date on which it first shipped multilayered wood flooring for export to the United States and the date on which the multilayered wood flooring was first entered, or withdrawn from warehouse, for consumption; (2) the volume of its first shipment and a statement that it made no subsequent shipments; and (3) the date of its first sale to an unaffiliated customer in the United States.<sup>8</sup>

The Department conducted U.S. Customs and Border Protection ("CBP") database queries and confirmed that Qingdao Barry's shipment of subject merchandise had entered the United States for consumption and that liquidation of such entries had been properly suspended for antidumping duties. The Department also confirmed by examining CBP data that Qingdao Barry's entries were made during the POR specified by the Department's regulations.<sup>9</sup>

<sup>4</sup> See Initiation Request at Attachment 1.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at Attachment 2.

<sup>9</sup> See Memorandum from Wendy Frankel, Director, Customs Liaison Unit, Enforcement and Compliance, To Abdelali Elouaradia, Director, AD/CVD Operations, Office IV, Enforcement and Compliance, Regarding "Confirmation of Entry—Multilayered Wood Flooring, From the People's Republic of China (A-570-970)," dated August 4, 2015 ("Customs Data"); see also Memorandum to the File entitled, "Initiation of Antidumping New Shipper Review of Multilayered Wood Flooring

**Initiation of New Shipper Review**

Pursuant to section 751(a)(2)(B) of the Act and 19 CFR 351.214(b), and after reviewing the information on the record, the Department finds that the request submitted by Qingdao Barry meets the threshold requirements for initiation of a new shipper review for the shipments of multilayered wood flooring from the PRC produced and exported by Qingdao Barry.<sup>10</sup> However, if the information supplied by Qingdao Barry is later found to be incorrect or insufficient during the course of this proceeding, the Department may rescind the review or apply adverse facts available pursuant to section 776 of the Act, depending upon the facts on the record. The Department intends to issue the preliminary results of this new shipper review no later than 180 days from the date of initiation, and the final results no later than 90 days from the issuance of the preliminary results.<sup>11</sup>

It is the Department's usual practice, in cases involving non-market economies, to require that a company seeking to establish eligibility for an antidumping duty rate separate from the country-wide rate provide evidence of *de jure* and *de facto* absence of government control over the company's export activities. Accordingly, the Department will issue a questionnaire to Qingdao Barry which will include a section requesting information with regard to the company's export activities for separate rates purposes. The review of the exporter will proceed if the response provides sufficient indication that it is not subject to either *de jure* or *de facto* government control with respect to its export of subject merchandise.

The Department will instruct CBP to allow, until the completion of the review, at the option of the importer, the posting of a bond or security in lieu of a cash deposit for each entry of the subject merchandise from Qingdao Barry, in accordance with section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(e). Because Qingdao Barry certified that it produced and exported the subject merchandise, the Department will apply the bonding

from the People's Republic of China: Qingdao Barry Flooring Co., Ltd. Initiation Checklist" ("Initiation Checklist") dated concurrently with this notice.

<sup>10</sup> See Initiation Checklist.

<sup>11</sup> See section 751(a)(2)(B)(iv) of the Act. Due to the unique circumstances of this new shipper review, the Department's ability to grant extension requests will be limited. See Memorandum from Robert Bolling, Program Manager, AD/CVD Operations, Office IV, Enforcement and Compliance, To The File, Regarding "Deadline Extensions—Multilayered Wood Flooring, From the People's Republic of China, dated concurrently with this notice.

privilege only for subject merchandise that the respondent both produced and exported. To assist in its analysis of the *bona fides* of Qingdao Barry's sales, upon initiation of this NSR, the Department will require Qingdao Barry to submit on an ongoing basis complete transaction information concerning any sales of subject merchandise to the United States that were made subsequent to the POR.

Interested parties requiring access to proprietary information in this new shipper review should submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305 and 19 CFR 351.306.

This initiation and notice are in accordance with section 751(a)(2)(B) of the Act and 19 CFR 351.214 and 19 CFR 351.221(c)(1)(i).

Dated: October 20, 2015.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2015-27156 Filed 10-23-15; 8:45 am]

**BILLING CODE 3510-DS-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### New England Fishery Management Council; Public Meeting

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

**ACTION:** Notice; public meeting.

**SUMMARY:** The New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Advisory Panel to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

**DATES:** This meeting will be held on Thursday, November 12, 2015 at 9:30 a.m.

**ADDRESSES:** The meeting will be held at the Holiday Inn by the Bay, 88 Spring Street, Portland, ME 04101; phone: (207) 775-2311; fax: (207) 772-4017.

*Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

**FOR FURTHER INFORMATION CONTACT:** Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465-0492.

**SUPPLEMENTARY INFORMATION:**

### Agenda

The items of discussion on the agenda are: The panel will receive an overview from the Groundfish Plan Development Team (PDT) on draft alternatives in Framework Adjustment 55 (FW 55) specifications, changes to the groundfish monitoring program, other management measures and draft impacts analysis. They also plan to develop recommendations to the Groundfish Committee regarding alternatives in FW 55. The panel will also develop recommendations to the Groundfish Committee for 2016 Council priorities. They will also discuss other business as necessary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

### Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465-0492, at least 5 days prior to the meeting date.

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

Dated: October 21, 2015.

**Tracey L. Thompson,**

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

[FR Doc. 2015-27134 Filed 10-23-15; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648-XE233**

#### Takes of Marine Mammals Incidental to Specified Activities; St. George Reef Light Station Restoration and Maintenance at Northwest Seal Rock, Del Norte County, California

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

**ACTION:** Notice; proposed incidental harassment authorization; request for comments.

**SUMMARY:** NMFS has received an application from the St. George Reef Lighthouse Preservation Society (Society), for an Incidental Harassment Authorization (Authorization) to take marine mammals, by harassment incidental to conducting aircraft operations, lighthouse renovation, and light maintenance activities on the St. George Reef Light Station on Northwest Seal Rock in the northeast Pacific Ocean. The proposed dates for this action would be late November 2015 through November 2016. Per the Marine Mammal Protection Act, we are requesting comments on our proposal to issue an Authorization to the Society to incidentally take, by Level B harassment only, marine mammals during the specified activity.

**DATES:** NMFS must receive comments and information on or before November 25, 2015.

**ADDRESSES:** Address comments on the application to Jolie Harrison, Division Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. The mailbox address for providing email comments is [ITP.Cody@noaa.gov](mailto:ITP.Cody@noaa.gov). Please include 0648-XE233 in the subject line. Comments sent via email to [ITP.Cody@noaa.gov](mailto:ITP.Cody@noaa.gov), including all attachments, must not exceed a 25-megabyte file size. NMFS is not responsible for email comments sent to addresses other than the one provided here.

*Instructions:* All submitted comments are a part of the public record and NMFS will post them to <http://www.nmfs.noaa.gov/pr/permits/incidental/research.htm> without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. To obtain an electronic copy of the application containing a list of the references used in this document, write to the previously mentioned address, telephone the contact listed here (see **FOR FURTHER INFORMATION CONTACT**), or visit the internet at: <http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm>.

The Environmental Assessment (EA) specific to conducting aircraft operations, restoration, and maintenance work on the light station is also available at the same internet



address. Information in the EA and this notice collectively provide the environmental information related to the proposed issuance of the Authorization for public review and comment. The public may also view documents cited in this notice, by appointment, during regular business hours, at the aforementioned address.

**FOR FURTHER INFORMATION CONTACT:**

Jeannine Cody, NMFS, Office of Protected Resources, NMFS (301) 427-8401.

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 101(a)(5)(D) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals of a species or population stock, by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if, after NMFS provides a notice of a proposed authorization to the public for review and comment: (1) NMFS makes certain findings; and (2) the taking is limited to harassment.

An Authorization shall be granted for the incidental taking of small numbers of marine mammals if NMFS finds that the taking will have a negligible impact on the species or stock(s), and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant). The Authorization must also set forth the permissible methods of taking; other means of effecting the least practicable adverse impact on the species or stock and its habitat; and requirements pertaining to the monitoring and reporting of such taking. NMFS has defined "negligible impact" in 50 CFR 216.103 as "an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

**Summary of Request**

On October 1, 2015, from the Society requesting that we issue an Authorization for the take of marine mammals, incidental to conducting restoration activities on the St. George Reef Light Station (Station) located on Northwest Seal Rock offshore of Crescent City, California in the northeast Pacific Ocean. NMFS determined the application complete and adequate on October 7, 2015.

The Society proposes to conduct aircraft operations, lighthouse renovation, and periodic maintenance on the Station's optical light system on a monthly basis. The proposed activity would occur on a monthly basis over one weekend, November 2015 through April 2016 and again for one weekend in November 2016. The following specific aspects of the proposed activities would likely result in the take of marine mammals: (1) Helicopter landings/takeoffs; (2) noise generated during restoration activities (*e.g.*, painting, plastering, welding, and glazing); (3) maintenance activities (*e.g.*, bulb replacement and automation of the light system); and (4) human presence. Thus, NMFS anticipates that take, by Level B harassment only, of California sea lions (*Zalophus californianus*); Pacific harbor seals (*Phoca vitulina*); Steller sea lions (*Eumetopias jubatus*) of the eastern U.S. Stock; and northern fur seals (*Callorhinus ursinus*) could result from the specified activity.

*Description of the Specified Activity*

**Overview**

To date, NMFS has issued four Authorizations to the Society for the conduct of the same activities from 2010 to 2015 (75 FR 4774, January 29, 2010; 76 FR 10564, February 25, 2011; 77 FR 8811, February 15, 2012; and 79 FR 6179, February 3, 2014). This is the Society's fifth request for an annual Authorization as their last Authorization expired on April 10, 2015.

The Station, listed in the National Park Service's National Register of Historic Places, is located on Northwest Seal Rock offshore of Crescent City, California in the northeast Pacific Ocean. The Station, built in 1892, rises 45.7 meters (m) (150 feet (ft)) above sea level. The structure consists of hundreds of granite blocks topped with a cast iron lantern room and covers much of the surface of the islet. The purpose of the project is to restore the lighthouse and to conduct annual and emergency maintenance on the Station's optical light system.

**Dates and Duration**

The Society proposes to conduct the activities (aircraft operations, lighthouse restoration, and maintenance activities) at a maximum frequency of one session per month. The proposed duration for each session would last no more than three days (*e.g.*, Friday, Saturday, and Sunday). The proposed Authorization, if issued, would be effective from November 27, 2015 through November 26, 2016 with restrictions on the Society conducting activities from May 1, 2016 to October 31, 2016. NMFS refers the reader to the Detailed Description of Activities section later in this notice for more information on the scope of the proposed activities.

**Specified Geographic Region**

The Station is located on a small, rocky islet (41°50'24" N., 124°22'06" W.) approximately nine kilometers (km) (6.0 miles (mi)) in the northeast Pacific Ocean, offshore of Crescent City, California (Latitude: 41°46'48" N.; Longitude: 124°14'11" W.). NWSR is approximately 91.4 m (300 ft) in diameter that peaks at 5.18 m (17 ft) above mean sea level.

*Detailed Description of Activities*

**Aircraft Operations**

Because Northwest Seal Rock has no safe landing area for boats, the proposed restoration activities would require the Society to transport personnel and equipment from the California mainland to Northwest Seal Rock by a small helicopter. Helicopter landings take place on top of the engine room (caisson) which is approximately 15 m (48 ft) above the surface of the rocks on Northwest Seal Rock. The Society plans to charter a Raven R44 helicopter, owned and operated by Air Shasta Rotor and Wing, LLC. The Raven R44, which seats three passengers and one pilot, is a compact-sized (1134 kilograms (kg), 2500 pounds (lbs)) helicopter with two-bladed main and tail rotors. Both sets of rotors are fitted with noise-attenuating blade tip caps that would decrease flyover noise.

The Society proposes to transport no more than 15 work crew members and equipment to Northwest Seal Rock for each session and estimates that each session would require no more than 36 helicopter landings/takeoffs per month. During landing, the helicopter would land on the caisson to allow the work crew members to disembark and retrieve their equipment located in a basket attached to the underside of the helicopter. The helicopter would then return to the mainland to pick up additional personnel and equipment.

Proposed schedule: The Society would conduct a maximum of 16 flights (eight arrivals and eight departures) for the first day. The first flight would depart from Crescent City Airport at approximately 9 a.m. for a 6-minute flight to Northwest Seal Rock. The helicopter would land and takeoff immediately after offloading personnel and equipment every 20 minutes (min). The total duration of the first day's aerial operations could last for approximately 3 hours (hrs) and 26 min and would end at approximately 12:34 p.m. Crew members would remain overnight at the Station and would not return to the mainland on the first day.

For the second day, the Society would conduct a maximum of 10 flights (five arrivals and five departures) to transport additional materials on and off the islet. The first flight would depart from Crescent City Airport at 9 a.m. for a 6-minute flight to Northwest Seal Rock. The total duration of the second day's aerial operations could last up to three hours.

For the final day of operations, the Society could conduct a maximum of eight helicopter flights (four arrivals and four departures) to transport the remaining crew members and equipment/material back to the Crescent City Airport. The total duration of the third day's helicopter operations in support of restoration could last up to 2 hrs and 14 min.

**Lighthouse Restoration Activities**

Restoration and maintenance activities would involve the removal of peeling paint and plaster, restoration of interior plaster and paint, refurbishing structural and decorative metal, reworking original metal support beams throughout the lantern room and elsewhere, replacing glass as necessary, upgrading the present electrical system; and annual light beacon maintenance.

**Emergency Light Maintenance**

If the beacon light fails, the Society proposes to send a crew of two to three people to the Station by helicopter to repair the beacon light. For each emergency repair event, the Society proposes to conduct a maximum of four flights (two arrivals and two departures) to transport equipment and supplies. The helicopter may remain on site or

transit back to shore and make a second landing to pick up the repair personnel.

In the case of an emergency repair between May 1, 2016, and October 31, 2016, the Society would consult with the NMFS' Western Regional Office (WRO) biologists to best determine the timing of the trips to the lighthouse, on a case-by-case basis, based upon the existing environmental conditions and the abundance and distribution of any marine mammals present on NWSR. The regional biologists would have real-time knowledge regarding the animal use and abundance of the NWSR at the time of the repair request and would make a decision regarding when the Society could conduct trips to the lighthouse during the emergency repair time window that would have the least practicable adverse impact to marine mammals. The WRO biologists would also ensure that the Society's request for incidental take during emergency repairs would not exceed the number of incidental take authorized in the proposed Authorization.

**Sound Sources and Sound Characteristics**

NMFS expects that acoustic stimuli resulting from the proposed helicopter operations; noise from maintenance and restoration activities; and human presence have the potential to harass marine mammals, incidental to the conduct of the proposed activities.

This section includes a brief explanation of the sound measurements frequently used in the discussions of acoustic effects in this notice. Sound pressure is the sound force per unit area, and is usually measured in micropascals (μPa), where 1 pascal (Pa) is the pressure resulting from a force of one newton exerted over an area of one square meter. Sound pressure level (SPL) is the ratio of a measured sound pressure and a reference level. The commonly used reference pressure is 1 μPa for under water, and the units for SPLs are dB re: 1 μPa. The commonly used reference pressure is 20 μPa for in air, and the units for SPLs are dB re: 20 μPa.

$$SPL \text{ (in decibels (dB))} = 20 \log \left( \frac{\text{pressure}}{\text{reference pressure}} \right)$$

SPL is an instantaneous measurement expressed as the peak, the peak-peak (p-p), or the root mean square (rms). Root

mean square is the square root of the arithmetic average of the squared instantaneous pressure values. All references to SPL in this document refer to the root mean square unless otherwise noted. SPL does not take into account the duration of a sound.

**R44 Helicopter Sound Characteristics**

Noise testing performed on the R44 Raven Helicopter, as required for Federal Aviation Administration approval, required an overflight at 150 m (492 ft) above ground level, 109 knots and a maximum gross weight of 1,134 kg (2,500 lbs). The noise levels measured on the ground at this distance and speed were 81.9 decibels (dB) re: 20 μPa (A-weighted) for the model R44 Raven I, or 81.0 dB re: 20 μPa (A-weighted) for the model R44 Raven II (NMFS, 2007).

Based on this information, we expect that the received sound levels at the landing area on the Station's caisson would increase above 81–81.9 dB re: 20 μPa (A-weighted).

**Restoration and Maintenance Sound Characteristics**

Any noise associated with these activities is likely to be from light construction (e.g., sanding, hammering, or use of hand drills). The Society proposes to confine all restoration activities to the existing structure which would occur on the upper levels of the Station. Pinnipeds hauled out on Northwest Seal Rock do not have access to the upper levels of the Station.

**Description of Marine Mammals in the Area of the Specified Activity**

Table 1 provides the following information: All marine mammal species with possible or confirmed occurrence in the proposed activity area; information on those species' regulatory status under the MMPA and the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*); abundance; occurrence and seasonality in the activity area. NMFS refers the public the 2015 draft NMFS Marine Mammal Stock Assessment Report available online at: <http://www.nmfs.noaa.gov/pr/sars/> for further information on the biology and distribution of these species.

TABLE 1—GENERAL INFORMATION ON MARINE MAMMALS THAT COULD POTENTIALLY HAUL OUT ON NORTHWEST SEAL ROCK, NOVEMBER 2015 THROUGH NOVEMBER 2016

Species	Stock	Regulatory status <sup>1 2</sup>	Stock abundance <sup>3</sup>	Occurrence and seasonality
California sea lion ( <i>Zalophus californianus</i> ) .....	U.S. ....	MMPA-NC ..... ESA-NL .....	296,750	Year-round presence.

TABLE 1—GENERAL INFORMATION ON MARINE MAMMALS THAT COULD POTENTIALLY HAUL OUT ON NORTHWEST SEAL ROCK, NOVEMBER 2015 THROUGH NOVEMBER 2016—Continued

Species	Stock	Regulatory status <sup>1 2</sup>	Stock abundance <sup>3</sup>	Occurrence and seasonality
Northern fur seal ( <i>Callorhinus ursinus</i> ) .....	California .....	MMPA-D .....	14,050	Rare.
	Breeding .....	ESA-NL .....		
Pacific harbor seal ( <i>Phoca vitulina</i> ) .....	California .....	MMPA-NC .....	30,968	Occasional, spring.
		ESA-NL .....		
Steller sea lion ( <i>Eumetopias jubatus</i> ) .....	Eastern Distinct .....	MMPA-D .....	60,131–74,448	Year-round presence.
	Population Segment .....	ESA-DL .....		

<sup>1</sup> MMPA: D = Depleted, S = Strategic, NC = Not Classified.

<sup>2</sup> ESA: EN = Endangered, T = Threatened, DL = Delisted, NL = Not listed.

<sup>3</sup> 2015 draft NMFS Stock Assessment Reports: Carretta *et al.* (2015) and Muto and Angliss (2015).

*Eastern Distinct Population Segment of Steller Sea Lions*

Steller sea lions consist of two distinct population segments: The western and eastern distinct population segments (DPS) divided at 144° West longitude (Cape Suckling, Alaska). The western segment of Steller sea lions inhabit central and western Gulf of Alaska, Aleutian Islands, as well as coastal waters and breed in Asia (e.g., Japan and Russia). The eastern segment includes sea lions living in southeast Alaska, British Columbia, California, and Oregon. The eastern DPS includes animals born east of Cape Suckling, AK (144° W) and the latest abundance estimate for the stock is 60,131 to 74,448 animals (Muto and Angliss, 2015).

Steller sea lions range along the North Pacific Rim from northern Japan to California (Loughlin *et al.*, 1984), with centers of abundance and distribution in the Gulf of Alaska and Aleutian Islands, respectively. The species is not known to migrate, but individuals disperse widely outside of the breeding season (late May through early July), thus potentially intermixing with animals from other areas.

The eastern distinct population segment of Steller sea lions breeds on rookeries located in southeast Alaska, British Columbia, Oregon, and California. There are no rookeries located in Washington state. Steller sea lions give birth in May through July and breeding commences a couple of weeks after birth. Pups are weaned during the winter and spring of the following year.

Despite the wide-ranging movements of juveniles and adult males in particular, exchange between rookeries by breeding adult females and males (other than between adjoining rookeries) appears low, although males have a higher tendency to disperse than females (NMFS, 1995; Trujillo *et al.*, 2004; Hoffman *et al.*, 2006). A northward shift in the overall breeding distribution has occurred, with a contraction of the range in southern

California and new rookeries established in southeastern Alaska (Pitcher *et al.*, 2007). Overall, counts of non-pups at trend sites in California and Oregon have been relatively stable or increasing slowly since the 1980s (Allen and Angliss, 2012).

Steller sea lion numbers at Northwest Seal Rock ranged from 20 to 355 animals (CCR, 2001). Counts of Steller sea lions during the spring (April–May), summer (June–August), and fall (September–October), averaged 68, 110, and 56, respectively (CCR, 2001). A multi-year survey at NWSR between 2000 and 2004 showed Steller sea lion numbers ranging from 175 to 354 in July (M. Lowry, NMFS/SWFSC, unpubl. data). The Society presumes that winter use of NWSR by Steller sea lion to be minimal, due to inundation of the natural portion of the island by large swells.

For the 2010 season, the Society reported that no Steller sea lions were present in the vicinity of Northwest Seal Rock during restoration activities (SGRLPS, 2010). Based on the monitoring report for the 2011 season, the maximum numbers of Steller sea lions present during the April and November 2011, work sessions was 2 and 150 animals, respectively (SGRLPS, 2012). During the 2012 season, the Society did not observe any Steller sea lions present on Northwest Seal Rock during restoration activities. The Society did not conduct any operations for the 2013–2014 and 2014–2015 seasons.

*California Sea Lion*

The estimated population of the U.S. stock of California sea lion is approximately 296,750 animals and the current maximum population growth rate is 12 percent (Carretta *et al.*, 2015).

California sea lion breeding areas are on islands located in southern California, in western Baja California, Mexico, and the Gulf of California. During the breeding season, most California sea lions inhabit southern

California and Mexico. Rookery sites in southern California are limited to the San Miguel Islands and the southerly Channel Islands of San Nicolas, Santa Barbara, and San Clemente (Carretta *et al.*, 2015). Males establish breeding territories during May through July on both land and in the water. Females come ashore in mid-May and June where they give birth to a single pup approximately four to five days after arrival and will nurse pups for about a week before going on their first feeding trip. Females will alternate feeding trips with nursing bouts until weaning between four and 10 months of age (NMML, 2010).

Adult and juvenile males will migrate as far north as British Columbia, Canada while females and pups remain in southern California waters in the non-breeding season. In warm water (El Niño) years, some females range as far north as Washington and Oregon, presumably following prey.

Crescent Coastal Research (CCR) conducted a three-year (1998–2000) survey of the wildlife species on NWSR for the Society. They reported that counts of California sea lions on NWSR varied greatly (from six to 541) during the observation period from April 1997 through July 2000. CCR reported that counts for California sea lions during the spring (April–May), summer (June–August), and fall (September–October), averaged 60, 154, and 235, respectively (CCR, 2001).

The most current counts for the month of July by NMFS (2000 through 2004) have been relatively low as the total number of California sea lions recorded in 2000 and 2003 was 3 and 11, respectively (M. Lowry, NMFS, SWFSC, unpublished data). Based on the monitoring report for the 2011 season, the maximum numbers of California sea lions present during the April and November, 2011 work sessions was 2 and 90 animals, respectively (SGRLPS, 2012). There were no California sea lions present

during the March, 2012 work session (SGRLPS, 2012).

#### *Northern Fur Seal*

Northern fur seals occur from southern California north to the Bering Sea and west to the Sea of Okhotsk and Honshu Island of Japan. NMFS recognizes two separate stocks of northern fur seals within U.S. waters: An Eastern Pacific stock distributed among sites in Alaska, British Columbia; and a San Miguel Island stock distributed along the west coast of the continental U.S. The estimated population of the San Miguel Island stock is 9,968 animals with a maximum population growth rate of 12 percent (Carretta *et al.*, 2015).

Northern fur seals may temporarily haul out on land at other sites in Alaska, British Columbia, and on islets along the west coast of the continental United States, but generally this occurs outside of the breeding season (Fiscus, 1983).

Northern fur seals breed in Alaska and migrate along the west coast during fall and winter. Due to their pelagic habitat, they are rarely seen from shore in the continental U.S., but individuals occasionally come ashore on islands well offshore (*i.e.*, Farallon Islands and Channel Islands in California). During the breeding season, approximately 74 percent of the worldwide population inhabits the Pribilof Islands in Alaska, with the remaining animals spread throughout the North Pacific Ocean (Lander and Kajimura, 1982).

CCR observed one male northern fur seal on Northwest Seal Rock in October, 1998 (CCR, 2001). It is possible that a few animals may use the island more often than indicated by the CCR surveys, if they were mistaken for other otariid species (*i.e.*, eared seals or fur seals and sea lions) (M. DeAngelis, NMFS, pers. comm.).

For the 2010, 2011, and 2012 work seasons, the Society has not observed any northern fur seals present on Northwest Seal Rock during restoration activities (SGRLPS, 2010; 2011; 2012).

#### *Pacific Harbor Seal*

The estimated population of the California stock of Pacific harbor seals is approximately 30,196 animals (Carretta *et al.*, 2015). There is no current estimate of abundance available for the Oregon/Washington stock (Carretta *et al.*, 2015).

The animals inhabit near-shore coastal and estuarine areas from Baja California, Mexico, to the Pribilof Islands in Alaska. Pacific harbor seals consist of two subspecies: *P. v. stejnegeri* in the western North Pacific, near Japan, and *P. v. richardsi* in the

northeast Pacific Ocean. The latter subspecies, recognized as three separate stocks, inhabits the west coast of the continental United States, including: The outer coastal waters of Oregon and Washington states; Washington state inland waters; and Alaska coastal and inland waters. Two of these stocks, the California stock and Oregon/Washington coast stock, of Pacific harbor seals are identified off the coast of Oregon and California for management purposes under the MMPA. However, the stock boundary is difficult to distinguish because of the continuous distribution of harbor seals along the west coast and any rigid boundary line is (to a greater or lesser extent) arbitrary, from a biological perspective (Carretta *et al.*, 2015). Due to the location of the proposed project which is situated near the border of Oregon and California, both stocks could be present within the proposed project area.

In California, over 500 harbor seal haulout sites are widely distributed along the mainland and offshore islands, and include rocky shores, beaches and intertidal sandbars (Lowry *et al.*, 2005). Harbor seals mate at sea and females give birth during the spring and summer, although, the pupping season varies with latitude. Females nurse their pups for an average of 24 days and are ready to swim minutes after being born. Harbor seal pupping takes place at many locations and rookery size varies from a few pups to many hundreds of pups. The nearest harbor seal rookery relative to the proposed project site is at Castle Rock National Wildlife Refuge, located approximately 965 m (0.6 mi) south of Point St. George, and 2.4 km (1.5 mi) north of the Crescent City Harbor in Del Norte County, California (USFWS, 2007).

CCR noted that harbor seal use of Northwest Seal Rock was minimal, with only one sighting of a group of six animals, during 20 observation surveys. They hypothesized that harbor seals may avoid the islet because of its distance from shore, relatively steep topography, and full exposure to rough and frequently turbulent sea swells. For the 2010 and 2011 seasons, the Society did not observe any Pacific harbor seals present on Northwest Seal Rock during restoration activities (SGRLPS, 2010; 2011). During the 2012 season, the Society reported sighting a total of two harbor seals present on Northwest Seal Rock (SGRLPS, 2012).

#### **Other Marine Mammals in the Proposed Action Area**

California (southern) sea otters (*Enhydra lutris nereis*), listed as threatened under the ESA and categorized as depleted under the MMPA, usually range in coastal waters within two km (1.2 mi) of the mainland shoreline. Neither CCR nor the Society has encountered California sea otters on Northwest Seal Rock during the course of the four-year wildlife study (CCR, 2001; SGRLPS, 2010; 2011; 2012)) nor has the Society encountered this species during the course of the previous four Authorizations. The U.S. Fish and Wildlife Service (USFWS) manages the sea otter and NMFS will not consider this species further in this notice.

#### **Potential Effects of the Specified Activities on Marine Mammals**

This section includes a summary and discussion of the ways that the types of stressors associated with the specified activity (*e.g.*, personnel presence) have been observed to impact marine mammals. This discussion may also include reactions that NMFS considers to rise to the level of a take and those that we do not consider to rise to the level of a take. This section serves as a background of potential effects and does not consider either the specific manner in which the applicant will carry out the activity or the mitigation that will be implemented, and how either of those will shape the anticipated impacts from this specific activity. The “Estimated Take by Incidental Harassment” section later in this document will include a quantitative analysis of the number of individuals that NMFS expects the Society to take during this activity. The “Negligible Impact Analysis” section will include the analysis of how this specific activity would impact marine mammals. NMFS will consider the content of the following sections: Estimated Take by Incidental Harassment; Proposed Mitigation; and Anticipated Effects on Marine Mammal Habitat, to draw conclusions regarding the likely impacts of this activity on the reproductive success or survivorship of individuals—and from that consideration—the likely impacts of this activity on the affected marine mammal populations or stocks.

Acoustic and visual stimuli generated by: (1) Helicopter landings/takeoffs; (2) noise generated during restoration activities (*e.g.*, painting, plastering, welding, and glazing); and (3) maintenance activities (*e.g.*, bulb replacement and automation of the light system) may have the potential to cause the following: Temporary or permanent

hearing impairment and/or behavioral disturbance (Southall, *et al.*, 2007).

#### *Potential Effects of Aircraft Presence and Noise on Marine Mammals*

Pinnipeds have the potential to be disturbed by airborne and underwater noise generated by the engine of the aircraft (Born, Riget, Dietz, & Andriashek, 1999; Richardson, Greene, Malme, & Thomson, 1995). Data on underwater TTS-onset in pinnipeds exposed to pulses are limited to a single study which exposed two California sea lions to single underwater pulses from an arc-gap transducer and found no measurable TTS following exposures up to 183 dB re: 1  $\mu$ Pa (peak-to-peak) (Finneran, Dear, Carder, & Ridgway, 2003).

Researchers have demonstrated temporary threshold shift (TTS) in certain captive odontocetes and pinnipeds exposed to strong sounds (reviewed in Southall *et al.*, 2007). In 2004, researchers measured auditory fatigue to airborne sound in harbor seals, California sea lions, and northern elephant seals after exposure to non-pulse noise for 25 minutes (Kastak, Southall, Holt, Kastak, & Schusterman, 2004). In the study, the harbor seal experienced approximately 6 dB of TTS at 99 dB re: 20  $\mu$ Pa. The authors identified onset of TTS in the California sea lion at 122 dB re: 20  $\mu$ Pa. The northern elephant seal experienced TTS-onset at 121 dB re: 20  $\mu$ Pa (Kastak, *et al.*, 2004).

There is a dearth of information on acoustic effects of helicopter overflights on pinniped hearing and communication (Richardson, *et al.*, 1995) and to NMFS' knowledge, there has been no specific documentation of TTS, let alone permanent threshold shift (PTS), in free-ranging pinnipeds exposed to helicopter operations during realistic field conditions (Baker, Jenz, & Chilvers, 2012; Scheidat *et al.*, 2011).

In 2008, NMFS issued an Authorization to the USFWS for the take of small numbers of Steller sea lions and Pacific harbor seals, incidental to rodent eradication activities on an islet offshore of Rat Island, AK conducted by helicopter. The 15-minute aerial treatment consisted of the helicopter slowly approaching the islet at an elevation of over 1,000 feet (304.8 m); gradually decreasing altitude in slow circles; and applying the rodenticide in a single pass and returning to Rat Island. The gradual and deliberate approach to the islet resulted in the sea lions present initially becoming aware of the helicopter and calmly moving into the water. Further, the USFWS reported that all responses fell well within the range

of Level B harassment (*i.e.*, limited, short-term displacement resulting from aircraft noise due to helicopter overflights).

As a general statement from the available information, pinnipeds exposed to intense (approximately 110 to 120 dB re: 20  $\mu$ Pa) non-pulse sounds often leave haulout areas and seek refuge temporarily (minutes to a few hours) in the water (Southall *et al.*, 2007). Per Richardson *et al.* (1995), approaching aircraft generally flush animals into the water and noise from a helicopter is typically directed down in a "cone" underneath the aircraft.

It is likely that the initial helicopter approach to Northwest Seal Rock would cause a subset, or all of the marine mammals hauled out to depart the rock and flush into the water. The physical presence of aircraft could also lead to non-auditory effects on marine mammals involving visual or other cues. Airborne sound from a low-flying helicopter or airplane may be heard by marine mammals while at the surface or underwater. In general, helicopters tend to be noisier than fixed wing aircraft of similar size and underwater sounds from aircraft are strongest just below the surface and directly under the aircraft. Noise from aircraft would not be expected to cause direct physical effects but have the potential to affect behavior. The primary factor that may influence abrupt movements of animals is engine noise, specifically changes in engine noise. Responses by mammals could include hasty dives or turns, change in course, or flushing and stampeding from a haul out site. There are few well documented studies of the impacts of aircraft overflight over pinniped haul out sites or rookeries, and many of those that exist, are specific to military activities (Efroymsen *et al.*, 2001).

Several factors complicate the analysis of long- and short-term effects for aircraft overflights. Information on behavioral effects of overflights by military aircraft (or component stressors) on most wildlife species is sparse. Moreover, models that relate behavioral changes to abundance or reproduction, and those that relate behavioral or hearing effects thresholds from one population to another are generally not available. In addition, the aggregation of sound frequencies, durations, and the view of the aircraft into a single exposure metric is not always the best predictor of effects and it may also be difficult to calculate. Overall, there has been no indication that single or occasional aircraft flying above pinnipeds in water cause long term displacement of these animals (Richardson *et al.*, 1995). The Lowest

Observed Adverse Effects Levels (LOAELs) are rather variable for pinnipeds on land, ranging from just over 150 m (492 ft) to about 2,000 m (6,562 ft) (Efroymsen *et al.*, 2001). A conservative (90th percentile) distance effects level is 1,150 m (3,773 ft). Most thresholds represent movement away from the overflight. Bowles and Stewart (1980) estimated an LOAEL of 305 m (1,000 ft) for helicopters (low and landing) in California sea lions and harbor seals observed on San Miguel Island, CA; animals responded to some degree by moving within the haul out and entering into the water, stampeding into the water, or clearing the haul out completely. Both species always responded with the raising of their heads. California sea lions appeared to react more to the visual cue of the helicopter than the noise.

If pinnipeds are present on Northwest Seal Rock, it is likely that a helicopter landing at the Station would cause some number of the pinnipeds on Northwest Seal Rock to flush; however, when present, they appear to show rapid habituation to helicopter landing and departure (Crescent Coastal Research, 2001; Guy Towers, SGRLPS, pers. com.). According to the CCR Report (2001), while up to 40 percent of the California and Steller sea lions present on Northwest Seal Rock have been observed to enter the water on the first of a series of helicopter landings, as few as zero percent have flushed on subsequent landings on the same date. In fact, the Society reported that during the November 2011 work session, Steller sea lions and California sea lions exhibited minimal ingress and egress from Northwest Seal Rock during helicopter approaches and departures (SGRLPS, 2011).

#### *Potential Effects of Human Presence on Marine Mammals*

The appearance of Society personnel may have the potential to cause Level B harassment of marine mammals hauled out on the small island in the proposed action area. Disturbance includes a variety of effects, including subtle to conspicuous changes in behavior, movement, and displacement. Disturbance may result in reactions ranging from an animal simply becoming alert to the presence of the Society's restoration personnel (*e.g.*, turning the head, assuming a more upright posture) to flushing from the haul-out site into the water. NMFS does not consider the lesser reactions to constitute behavioral harassment, or Level B harassment takes, but rather assumes that pinnipeds that move greater than 1 meter (m) (3.3 feet (ft)) or

change the speed or direction of their movement in response to the presence of surveyors are behaviorally harassed, and thus subject to Level B taking. Animals that respond to the presence of the Society's restoration personnel by becoming alert, but do not move or change the nature of locomotion as described, are not considered to have been subject to behavioral harassment.

Reactions to human presence, if any, depend on species, state of maturity, experience, current activity, reproductive state, time of day, and many other factors (Richardson *et al.*, 1995; Wartzok *et al.*, 2004; Southall *et al.*, 2007; Weilgart, 2007). These behavioral reactions are often shown as: Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior; avoidance of areas; and/or flight responses (*e.g.*, pinnipeds flushing into the water from haul-outs or rookeries). If a marine mammal does react briefly to human presence by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if visual stimuli from human presence displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.*, Lusseau and Bejder, 2007; Weilgart, 2007).

Disturbances resulting from human activity can impact short- and long-term pinniped haul out behavior (Renouf *et al.*, 1981; Schneider and Payne, 1983; Terhune and Almon, 1983; Allen *et al.*, 1984; Stewart, 1984; Suryan and Harvey, 1999; Mortenson *et al.*, 2000; and Kucey and Trites, 2006). Numerous studies have shown that human activity can flush harbor seals off haulout sites (Allen *et al.*, 1984; Calambokidis *et al.*, 1991; Suryan and Harvey, 1999; and Mortenson *et al.*, 2000) or lead to Hawaiian monk seals (*Monachus schauinslandi*) avoidance of beach areas. The Hawaiian monk seal avoiding beaches (Kenyon, 1972). In one case, human disturbance appeared to cause Steller sea lions to desert a breeding area at Northeast Point on St. Paul Island, Alaska (Kenyon, 1962).

In cases where vessels actively approached marine mammals (*e.g.*, whale watching or dolphin watching boats), scientists have documented that animals exhibit altered behavior such as increased swimming speed, erratic movement, and active avoidance

behavior (Bursk, 1983; Acevedo, 1991; Baker and MacGibbon, 1991; Trites and Bain, 2000; Williams *et al.*, 2002; Constantine *et al.*, 2003), reduced blow interval (Ritcher *et al.*, 2003), disruption of normal social behaviors (Lusseau, 2003; 2006), and the shift of behavioral activities which may increase energetic costs (Constantine *et al.*, 2003; 2004).

In 1997, Henry and Hammil (2001) conducted a study to measure the impacts of small boats (*i.e.*, kayaks, canoes, motorboats and sailboats) on harbor seal haulout behavior in Metis Bay, Quebec, Canada. During that study, the authors noted that the most frequent disturbances (n=73) were caused by lower speed, lingering kayaks, and canoes (33.3 percent) as opposed to motorboats (27.8 percent) conducting high speed passes. The seal's flight reactions could be linked to a surprise factor by kayaks-canoes which approach slowly, quietly and low on water making them look like predators. However, the authors note that once the animals were disturbed, there did not appear to be any significant lingering effect on the recovery of numbers to their pre-disturbance levels. In conclusion, the study showed that boat traffic at current levels has only a temporary effect on the haulout behavior of harbor seals in the Metis Bay area.

In 2004, Johnson and Acevedo-Gutierrez (2007) evaluated the efficacy of buffer zones for watercraft around harbor seal haulout sites on Yellow Island, Washington. The authors estimated the minimum distance between the vessels and the haul-out sites; categorized the vessel types; and evaluated seal responses to the disturbances. During the course of the seven-weekend study, the authors recorded 14 human-related disturbances which were associated with stopped powerboats and kayaks. During these events, hauled out seals became noticeably active and moved into the water. The flushing occurred when stopped kayaks and powerboats were at distances as far as 453 and 1,217 ft (138 and 371 m) respectively. The authors note that the seals were unaffected by passing powerboats, even those approaching as close as 128 ft (39 m), possibly indicating that the animals had become tolerant of the brief presence of the vessels and ignored them. The authors reported that on average, the seals quickly recovered from the disturbances and returned to the haulout site in less than or equal to 60 minutes. Seal numbers did not return to pre-disturbance levels within 180 minutes of the disturbance less than one quarter of the time observed. The study

concluded that the return of seal numbers to pre-disturbance levels and the relatively regular seasonal cycle in abundance throughout the area counter the idea that disturbances from powerboats may result in site abandonment (Johnson and Acevedo-Gutierrez, 2007). As a general statement from the available information, pinnipeds exposed to intense (approximately 110 to 120 decibels re: 20  $\mu$ Pa) non-pulsed sounds often leave haulout areas and seek refuge temporarily (minutes to a few hours) in the water (Southall *et al.*, 2007).

#### Stampede

There are other ways in which disturbance, as described previously, could result in more than Level B harassment of marine mammals. They are most likely to be consequences of stampeding, a potentially dangerous occurrence in which large numbers of animals succumb to mass panic and rush away from a stimulus. These situations are: (1) Falling when entering the water at high-relief locations; (2) extended separation of mothers and pups; and (3) crushing of pups by large males during a stampede. However, NMFS does not expect any of these scenarios to occur at Northwest Seal Rock. There is the risk of injury if animals stampede towards shorelines with precipitous relief (*e.g.*, cliffs). However, there are no cliffs on Northwest Seal Rock. The haulout sites consist of ridges with unimpeded and non-obstructive access to the water. If disturbed, the small number of hauled-out adult animals may move toward the water without risk of encountering barriers or hazards that would otherwise prevent them from leaving the area. Moreover, the proposed area would not be crowded with large numbers of Steller sea lions, further eliminating the possibility of potentially injurious mass movements of animals attempting to vacate the haulout. Thus, in this case, NMFS considers the risk of injury, serious injury, or death to hauled-out animals as very low.

#### Anticipated Effects on Marine Mammal Habitat

The only habitat modification associated with the proposed activity is the restoration of a light station which would occur on the upper levels of Northwest Seal Rock which are not used by marine mammals. Thus, NMFS does not expect that the proposed activity would have any effects on marine mammal habitat and NMFS expects that there will be no long- or short-term physical impacts to pinniped habitat on Northwest Seal Rock.

The Society would remove all waste, discarded materials and equipment from the island after each visit. The proposed activities will not result in any permanent impact on habitats used by marine mammals, including prey species and foraging habitat. The main impact associated with the proposed activity will be temporarily elevated noise levels and the associated direct effects on marine mammals (*i.e.*, the potential for temporary abandonment of the site), previously discussed in this notice.

NMFS does not anticipate that the proposed restoration activities would result in any permanent effects on the habitats used by the marine mammals in the proposed area, including the food sources they use (*i.e.*, fish and invertebrates). Based on the preceding discussion, NMFS does not anticipate that the proposed activity would have any habitat-related effects that could cause significant or long-term consequences for individual marine mammals or their populations.

#### Proposed Mitigation

In order to issue an incidental take authorization under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant).

**Time and Frequency:** The Society would conduct restoration activities at maximum of once per month between November 27, 2015, through November 26, 2016. Each restoration session would last no more than three days. Maintenance of the light beacon would occur only in conjunction with restoration activities. The Society would not conduct restoration activities between May 1, 2016 through October 31, 2016.

**Helicopter Approach and Timing Techniques:** The Society would ensure that its helicopter approach patterns to the Station and timing techniques do not disturb marine mammals as most practicable. To the extent possible, the helicopter should approach Northwest Seal Rock when the tide is too high for the marine mammals to haul-out on Northwest Seal Rock.

Since the most severe impacts (stampede) precede rapid and direct helicopter approaches, the Society's initial approach to the Station must be offshore from the island at a relatively

high altitude (*e.g.*, 800–1,000 ft, or 244–305 m). Before the final approach, the helicopter shall circle lower, and approach from area with the lowest pinniped density. If for any safety reasons (*e.g.*, wind condition) the Society cannot conduct these types of helicopter approach and timing techniques, they must postpone the restoration and maintenance activities for that day.

**Avoidance of Visual and Acoustic Contact with People on Island:** The Society would instruct its members and restoration crews to avoid making unnecessary noise and not expose themselves visually to pinnipeds around the base of the Station. Although CCR reported no impacts from these activities in the 2001 CCR study, it is relatively simple for the Society to avoid this potential impact. The door to the lower platform (which is used at times by pinnipeds) shall remain closed and barricaded to all tourists and other personnel.

#### Mitigation Conclusions

NMFS has carefully evaluated the Society's proposed mitigation measures in the context of ensuring that we prescribe the means of affecting the least practicable impact on the affected marine mammal species and stocks and their habitat. The evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

Any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed here:

1. Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).
2. A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to vessel or visual presence that NMFS expects to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).
3. A reduction in the number of times (total number or number at biologically

important time or location) individuals exposed to vessel or visual presence that NMFS expects to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

4. A reduction in the intensity of exposures (either total number or number at biologically important time or location) to vessel or visual presence that NMFS expects to result in the take of marine mammals (this goal may contribute to a, above, or to reducing the severity of harassment takes only).

5. Avoidance or minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.

6. For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on the evaluation of the Society's proposed measures, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

#### Proposed Monitoring

In order to issue an incidental take authorization for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth "requirements pertaining to the monitoring and reporting of such taking." The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for Authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that NMFS expects to be present in the proposed action area.

The Society submitted a marine mammal monitoring plan in section 13 of their Authorization application. NMFS or the Society may modify or supplement the plan based on comments or new information received from the public during the public comment period.

Monitoring measures prescribed by NMFS should accomplish one or more of the following general goals:



1. An increase in our understanding of the likely occurrence of marine mammal species in the vicinity of the action, (*i.e.*, presence, abundance, distribution, and/or density of species).

2. An increase in our understanding of the nature, scope, or context of the likely exposure of marine mammal species to any of the potential stressor(s) associated with the action (*e.g.*, sound or visual stimuli), through better understanding of one or more of the following: The action itself and its environment (*e.g.*, sound source characterization, propagation, and ambient noise levels); the affected species (*e.g.*, life history or dive pattern); the likely co-occurrence of marine mammal species with the action (in whole or part) associated with specific adverse effects; and/or the likely biological or behavioral context of exposure to the stressor for the marine mammal (*e.g.*, age class of exposed animals or known pupping, calving or feeding areas).

3. An increase in our understanding of how individual marine mammals respond (behaviorally or physiologically) to the specific stressors associated with the action (in specific contexts, where possible, *e.g.*, at what distance or received level).

4. An increase in our understanding of how anticipated individual responses, to individual stressors or anticipated combinations of stressors, may impact either: The long-term fitness and survival of an individual; or the population, species, or stock (*e.g.*, through effects on annual rates of recruitment or survival).

5. An increase in our understanding of how the activity affects marine mammal habitat, such as through effects on prey sources or acoustic habitat (*e.g.*, through characterization of longer-term contributions of multiple sound sources to rising ambient noise levels and assessment of the potential chronic effects on marine mammals).

6. An increase in understanding of the impacts of the activity on marine mammals in combination with the impacts of other anthropogenic activities or natural factors occurring in the region.

7. An increase in our understanding of the effectiveness of mitigation and monitoring measures.

8. An increase in the probability of detecting marine mammals (through improved technology or methodology), both specifically within the safety zone (thus allowing for more effective implementation of the mitigation) and in general, to better achieve the above goals.

As part of its Authorization application, the Society proposes to sponsor marine mammal monitoring, in order to implement the mitigation measures that require real-time monitoring, and to satisfy the monitoring requirements of the proposed Authorization. These include:

At least once during the period between November 27, 2015 through November 26, 2016, a qualified biologist shall be present during all three workdays at the Station. The qualified biologist hired will be subject to approval by us and they shall document use of the island by the pinnipeds, frequency, (*i.e.*, dates, time, tidal height, species, numbers present, and any disturbances), and note any responses to potential disturbances.

Aerial photographic surveys may provide the most accurate means of documenting species composition, age and sex class of pinnipeds using the project site during human activity periods. The Society should complete aerial photo coverage of the island from the same helicopter used to transport the Society's personnel to the island during restoration trips. The Society would take photographs of all marine mammals hauled out on the island at an altitude greater than 300 m (984 ft) by a skilled photographer, prior to the first landing on each visit included in the monitoring program. Photographic documentation of marine mammals present at the end of each three-day work session shall also be made for a before and after comparison. These photographs will be forwarded to a biologist capable of discerning marine mammal species. Data shall be provided to us in the form of a report with a data table, any other significant observations related to marine mammals, and a report of restoration activities (see Reporting). The original photographs can be made available to us or other marine mammal experts for inspection and further analysis.

Proposed monitoring requirements in relation to the Society's proposed activities would include species counts, numbers of observed disturbances, and descriptions of the disturbance behaviors during the restoration activities, including location, date, and time of the event. In addition, the Society would record observations regarding the number and species of any marine mammals either observed in the water or hauled out.

The Society can add to the knowledge of pinnipeds in the proposed action area by noting observations of: (1) Unusual behaviors, numbers, or distributions of pinnipeds, such that any potential follow-up research can be conducted by

the appropriate personnel; (2) tag-bearing carcasses of pinnipeds, allowing transmittal of the information to appropriate agencies and personnel; and (3) rare or unusual species of marine mammals for agency follow-up.

If at any time injury, serious injury, or mortality of the species for which take is authorized should occur, or if take of any kind of any other marine mammal occurs, and such action may be a result of the Society's activities, the Society would suspend survey activities and contact NMFS immediately to determine how best to proceed to ensure that another injury or death does not occur and to ensure that the applicant remains in compliance with the MMPA.

#### *Summary of Previous Monitoring*

The Society complied with the mitigation and monitoring required under the previous authorizations (2010–2013). They did not conduct any operations for the 2013 season. However, in compliance with the 2012 Authorization, the Society submitted a final report on the activities at the Station, covering the period of February 15, 2012 through April 30, 2012. During the effective dates of the 2012 IHA, the Society conducted one work session in March, 2012. The Society's aircraft operations and restoration activities on NWSR did not exceed the activity levels analyzed under the 2012 authorization. During the March 2012 work session, the Society observed two harbor seals hauled out on Northwest Seal Rock. Both animals (a juvenile and an adult) departed the rock, entered the water, and did not return to the Station during the duration of the activities.

#### **Proposed Reporting**

The Society would submit a draft report to NMFS' Office of Protected Resources no later than 90 days after the expiration of the proposed Authorization, if issued. The report will include a summary of the information gathered pursuant to the monitoring requirements set forth in the proposed Authorization. The Society will submit a final report to the NMFS Director, Office of Protected Resources within 30 days after receiving comments from NMFS on the draft report. If the Society receives no comments from NMFS on the report, NMFS will consider the draft report to be the final report.

The report will describe the operations conducted and sightings of marine mammals near the proposed project. The report will provide full documentation of methods, results, and interpretation pertaining to all monitoring. The report will provide:



1. A summary and table of the dates, times, and weather during all research activities.

2. Species, number, location, and behavior of any marine mammals observed throughout all monitoring activities.

3. An estimate of the number (by species) of marine mammals exposed to human presence associated with the Society's activities.

4. A description of the implementation and effectiveness of the monitoring and mitigation measures of the Authorization and full documentation of methods, results, and interpretation pertaining to all monitoring.

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the authorization, such as an injury (Level A harassment), serious injury, or mortality (e.g., stampede), Society personnel shall immediately cease the specified activities and immediately report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301-427-8401 and the Assistant Western Regional Stranding Coordinator at (562) 980-3264. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Description and location of the incident (including water depth, if applicable);
- Environmental conditions (e.g., wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

The Society shall not resume its activities until NMFS is able to review the circumstances of the prohibited take. We will work with the Society to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. The Society may not resume their activities until notified by us via letter, email, or telephone.

In the event that the Society discovers an injured or dead marine mammal, and the marine mammal observer determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.*, in less than a moderate state of decomposition as we describe in the next paragraph), the Society will immediately report the

incident to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301-427-8401 and the Assistant Western Regional Stranding Coordinator at (562) 980-3264. The report must include the same information identified in the paragraph above this section. Activities may continue while NMFS reviews the circumstances of the incident. NMFS would work with the Society to determine whether modifications in the activities are appropriate.

In the event that the Society discovers an injured or dead marine mammal, and the lead visual observer determines that the injury or death is not associated with or related to the authorized activities (e.g., previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), the Society will report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301-427-8401 and the Assistant Western Regional Stranding Coordinator at (562) 980-3264 within 24 hours of the discovery. Society personnel will provide photographs or video footage (if available) or other documentation of the stranded animal sighting to us. The Society can continue their survey activities while NMFS reviews the circumstances of the incident.

#### **Estimated Take by Incidental Harassment**

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

All anticipated takes would be by Level B harassment, involving temporary changes in behavior. NMFS expects that the proposed mitigation and monitoring measures would minimize the possibility of injurious or lethal takes. NMFS considers the potential for take by injury, serious injury, or mortality as remote. NMFS expects that the presence of Society personnel could disturb of animals hauled out on Northwest Seal Rock and that the animals may alter their behavior or attempt to move away from the Society's personnel.

As discussed earlier, NMFS considers an animal to have been harassed if it

moved greater than 1 m (3.3 ft) in response to the Society's presence or if the animal was already moving and changed direction and/or speed, or if the animal flushed into the water. NMFS does not consider animals that became alert without such movements as harassed.

Based on the Society's previous monitoring reports, NMFS estimates that approximately 960 California sea lions (calculated by multiplying the maximum number California sea lions present on NWSR (160) by 6 months of the restoration and maintenance activities), 172 Steller sea lions (NMFS' estimate of the maximum number of Steller sea lions that could be present on NWSR with a 95-percent confidence interval), 36 Pacific harbor seals (calculated by multiplying the maximum number of harbor seals present on NWSR (6) by 6 months), and 6 northern fur seals (calculated by multiplying the maximum number of northern fur seals present on NWSR (1) by 6 months) could be potentially affected by Level B behavioral harassment over the course of the Authorization. NMFS bases these estimates of the numbers of marine mammals that might be affected on consideration of the number of marine mammals that could be disturbed appreciably by approximately 51 hours of aircraft operations during the course of the activity. These incidental harassment take numbers represent approximately 0.32 percent of the U.S. stock of California sea lion, 0.42 percent of the eastern U.S. stock of Steller sea lion, 0.11 percent of the California stock of Pacific harbor seals, and 0.05 percent of the San Miguel Island stock of northern fur seal. However, actual take may be slightly less if animals decide to haul out at a different location for the day or if animals are foraging at the time of the survey activities.

Because of the required mitigation measures and the likelihood that some pinnipeds will avoid the area, NMFS does not expect any injury or mortality to pinnipeds to occur and NMFS has not authorized take by Level A harassment for this proposed activity.

#### **Encouraging and Coordinating Research**

The Society would share observations and counts of marine mammals and all observed disturbances to the appropriate state and federal agencies at the conclusion of the survey.

## Analysis and Preliminary Determinations

### Negligible Impact

Negligible impact is “an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival” (50 CFR 216.103). The lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population level effects) forms the basis of a negligible impact finding. An estimate of the number of Level B harassment takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be “taken” through behavioral harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.*, intensity, duration), the context of any responses (*e.g.*, critical reproductive time or location, migration), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, and effects on habitat.

Although the Society’s survey activities may disturb a small number of marine mammals hauled out on Northwest Seal Rock, NMFS expects those impacts to occur to a small, localized group of animals for a limited duration (*e.g.*, six hours in one day). Marine mammals would likely become alert or, at most, flush into the water in reaction to the presence of the Society’s personnel during the proposed activities. Disturbance will be limited to a short duration, allowing marine mammals to reoccupy Northwest Seal Rock within a short amount of time. Thus, the proposed action is unlikely to result in long-term impacts such as permanent abandonment of the area because of the availability of alternate areas for pinnipeds to avoid the resultant acoustic and visual disturbances from the restoration activities and helicopter operations. Results from previous monitoring reports also show that the pinnipeds returned Northwest Seal Rock and did not permanently abandon haul-out sites after the Society conducted their activities.

The Society’s activities would occur during the least sensitive time (*e.g.*, November through April, outside of the pupping season) for hauled out pinnipeds on Northwest Seal Rock. Thus, pups or breeding adults would not be present during the proposed one-day survey.

Moreover, the Society’s mitigation measures regarding helicopter approaches and restoration site ingress and egress would minimize the potential for stampedes and large-scale movements. Thus, the potential for large-scale movements and stampede leading to injury, serious injury, or mortality is low.

Any noise attributed to the Society’s proposed helicopter operations on NWSR would be short-term (approximately 5 min per trip). We would expect the ambient noise levels to return to a baseline state when helicopter operations have ceased for the day. As the helicopter landings take place 15 m (48 ft) above the surface of the rocks on NWSR, NMFS presumes that the received sound levels would increase above 81–81.9 dB re: 20  $\mu$ Pa (A-weighted) at the landing pad. However, we do not expect that the increased received levels of sound from the helicopter would cause TTS or PTS because the pinnipeds would flush before the helicopter approached NWSR; thus increasing the distance between the pinnipeds and the received sound levels on NWSR during the proposed action.

If pinnipeds are present on Northwest Seal Rock, Level B behavioral harassment of pinnipeds may occur during helicopter landing and takeoff from NWSR due to the pinnipeds temporarily moving from the rocks and lower structure of the Station into the sea due to the noise and appearance of helicopter during approaches and departures. It is expected that all or a portion of the marine mammals hauled out on the island will depart the rock and slowly move into the water upon initial helicopter approaches. The movement to the water would be gradual due to the required controlled helicopter approaches (see “Proposed Mitigation” for more details), the small size of the aircraft, the use of noise-attenuating blade tip caps on the rotors, and behavioral habituation on the part of the animals as helicopter trips continue throughout the day. During the sessions of helicopter activity, if present on NWSR, some animals may be temporarily displaced from the island and either raft in the water or relocate to other haul-outs.

Sea lions have shown habituation to helicopter flights within a day at the project site and most animals are expected to return soon after helicopter activities cease for that day. By clustering helicopter arrival/departures within a short time period, we expect animals present to show less response to subsequent landings. NMFS anticipates no impact on the population size or

breeding stock of Steller sea lions, California sea lions, Pacific harbor seals, or northern fur seals.

In summary, NMFS anticipates that impacts to hauled-out pinnipeds during the Society’s proposed helicopter operations and restoration/maintenance activities would be behavioral harassment of limited duration (*i.e.*, less than three days a month) and limited intensity (*i.e.*, temporary flushing at most). NMFS does not expect stampeding, and therefore injury or mortality to occur (see “Proposed Mitigation” for more details). Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the Society’s proposed survey activities will have a negligible impact on the affected marine mammal species or stocks.

### Small Numbers

As mentioned previously, NMFS estimates that the Society’s proposed activities could potentially affect, by Level B harassment only, four species of marine mammal under our jurisdiction. For each species, these estimates are small numbers (each, less than or equal to one percent) relative to the population size. These incidental harassment take numbers represent approximately 0.32 percent of the U.S. stock of California sea lion, 0.42 percent of the eastern U.S. stock of Steller sea lion, 0.11 percent of the California stock of Pacific harbor seals, and 0.05 percent of the San Miguel Island stock of northern fur seal.

Based on the analysis contained in this notice of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS preliminarily finds that the Society’s proposed activities would take small numbers of marine mammals relative to the populations of the affected species or stocks.

### Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

### Endangered Species Act (ESA)

NMFS does not expect that the Society's proposed helicopter operations and restoration/maintenance activities would affect any species listed under the ESA. Therefore, NMFS has determined that a section 7 consultation under the ESA is not required.

### National Environmental Policy Act (NEPA)

To meet our NEPA requirements for the issuance of an Authorization to the Society, NMFS has prepared an Environmental Assessment (EA) in 2010 that was specific to conducting aircraft operations and restoration and maintenance work on the St. George Reef Light Station. The EA, titled "Issuance of an Incidental Harassment Authorization to Take Marine Mammals by Harassment Incidental to Conducting Aircraft Operations, Lighthouse Restoration and Maintenance Activities on St. George Reef Lighthouse Station in Del Norte County, California," evaluated the impacts on the human environment of our authorization of incidental Level B harassment resulting from the specified activity in the specified geographic region. At that time, NMFS concluded that issuance of an annual Authorization would not significantly affect the quality of the human environment and issued a Finding of No Significant Impact (FONSI) for the 2010 EA regarding the Society's activities. In conjunction with the Society's 2015 application, NMFS has again reviewed the 2010 EA and determined that there are no new direct, indirect or cumulative impacts to the human and natural environment associated with the IHA requiring evaluation in a supplemental EA and NMFS, therefore, intends to preliminarily reaffirm the 2010 FONSI. An electronic copy of the EA and the FONSI for this activity is available upon request (see ADDRESSES).

### Proposed Authorization

As a result of these preliminary determinations, NMFS proposes issuing an Authorization to the Society for conducting helicopter operations and restoration activities on the St. George Light Station in the northeast Pacific Ocean, November 27, 2015, through November 26 2016, provided they incorporate the previously mentioned mitigation, monitoring, and reporting requirements.

### Draft Proposed Authorization

This section contains the draft text for the proposed Authorization. NMFS proposes to include this language in the Authorization if issued.

### Proposed Authorization Language

The St. George Reef Lighthouse Preservation Society (Society), P.O. Box 577, Crescent City, CA 95531, is hereby authorized under section 101(a)(5)(D) of the Marine Mammal Protection Act (16 U.S.C. 1371(a)(5)(D)) and 50 CFR 216.107, to harass marine mammals incidental to conducting helicopter operations and restoration and maintenance work on the St. George Reef Light Station (Station) on Northwest Seal Rock in the northeast Pacific Ocean.

1. This Incidental Harassment Authorization (IHA) is valid from November 27, 2015, through November 26, 2016. The Society may not conduct operations from May 1, 2016 through October 31, 2016.

2. This IHA is valid only for activities associated with helicopter operations and restoration and maintenance activities (See items 2(a)–(d)) on the Station on Northwest Seal Rock (41°50'24" N., 124°22'06" W.) in the northeast Pacific Ocean.

a. The use of a small, compact, 4-person helicopter with two-bladed main and tail rotors fitted with noise-attenuating blade tip caps to transit to and from Northwest Seal Rock;

b. Restoration activities (e.g., painting, plastering, welding, and glazing) conducted on the Station;

c. Maintenance activities (e.g., bulb replacement and automation of the light system) conducted on the Station; and

d. Emergency repair events (e.g., the failure of the PATON beacon light) outside of the three-day work session.

### 3. General Conditions

a. A copy of this IHA must be in the possession of the Society, its designees, and work crew personnel operating under the authority of this IHA.

b. The species authorized for taking are the California sea lion (*Zalophus californianus*), Pacific Harbor seal (*Phoca vitulina*), the eastern Distinct Population Segment of Steller sea lion (*Eumetopias jubatus*), and the eastern Pacific stock of northern fur seal (*Callorhinus ursinus*).

c. The taking, by Level B harassment only, is limited to the species listed in condition 3(b). Authorized take: California sea lion (960); Steller sea lion (172); Pacific harbor seal (36); and northern fur seal (6).

d. The taking by Level A harassment, injury or death of any of the species listed in item 3(b) of the Authorization or the taking by harassment, injury or death of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this IHA.

e. In the case of an emergency repair event (i.e., failure of the PATON beacon light) between May 1, 2016 through October 31, 2016, the Society will consult with the ARA, Western Region, NMFS, to best determine the timing of an emergency repair trip to the Station.

a. The Western Region NMFS marine mammal biologist will make a decision regarding when the Society can schedule helicopter trips to the Northwest Seal Rock during the emergency repair time window and will ensure that such operations will have the least practicable adverse impact to marine mammals.

b. The ARA, Western Region, NMFS will also ensure that the Society's request for incidental take during an emergency repair event would not exceed the number of incidental take authorized in this IHA.

### 4. Cooperation

The holder of this Authorization is required to cooperate with the NMFS and any other Federal, state, or local agency authorized to monitor the impacts of the activity on marine mammals.

### 5. Mitigation Measures

In order to ensure the least practicable impact on the species listed in condition 3(b), the holder of this Authorization is required to:

a. Conduct restoration and maintenance activities at the Station at a maximum of one session per month between November 27, 2015, through November 26, 2016. Each restoration session will be no more than three days in duration. Maintenance of the light beacon will occur only in conjunction with the monthly restoration activities.

b. Ensure that helicopter approach patterns to the Northwest Seal Rock will be such that the timing techniques are least disturbing to marine mammals. To the extent possible, the helicopter should approach Northwest Seal Rock when the tide is too high for the marine mammals to haul-out on Northwest Seal Rock.

c. Avoid rapid and direct approaches by the helicopter to the station by approaching Northwest Seal Rock at a relatively high altitude (e.g., 800–1,000 ft; 244–305 m). Before the final approach, the helicopter shall circle lower, and approach from area where the density of pinnipeds is the lowest. If for any safety reasons (e.g., wind conditions or visibility) such helicopter approach and timing techniques cannot be achieved, the Society must abort the restoration and maintenance session for that day.

d. Provide instructions to the Society's members, the restoration crew, and if applicable, to tourists, on appropriate conduct when in the vicinity of hauled-out marine mammals. The Society's members, the restoration crew, and if applicable, tourists, will avoid making unnecessary noise while on Northwest Seal Rock and must not view pinnipeds around the base of the Station.

e. Ensure that the door to the Station's lower platform shall remain closed and barricaded at all times.

#### 6. Monitoring

The holder of this Authorization is required to:

a. Have a NMFS-approved biologist present during all three workdays at the Station at least once during the period of November 27, 2015, through November 26, 2016. This requirement may be modified depending on the results of the monthly monitoring reports. The biologist shall document use of the island by the marine mammals (*i.e.*, dates, time, tidal height, species, numbers present, frequency of use, weather conditions, and any disturbances), and note any responses to potential disturbances.

b. Record the date, time, and location (or closest point of ingress) of each visit to the Northwest Seal Rock.

c. Collect the following information for each visit:

i. Information on the numbers (by species) of marine mammals observed during the activities;

ii. The estimated number of marine mammals (by species) that may have been harassed during the activities;

iii. Any behavioral responses or modifications of behaviors that may be attributed to the specific activities (*e.g.*, flushing into water, becoming alert and moving, rafting); and

iv. Information on the weather, including the tidal state and horizontal visibility.

d. Employ a skilled, aerial photographer to document marine mammals hauled out on Northwest Seal Rock for comparing marine mammal presence on Northwest Seal Rock pre- and post-restoration.

i. The photographer will complete a photographic survey of Northwest Seal Rock using the same helicopter that will transport Society personnel to the island during restoration trips.

ii. For a pre-restoration survey, photographs of all marine mammals hauled-out on the island shall be taken at an altitude greater than 300 m (984 ft) during the first arrival flight to Northwest Seal Rock.

iii. For the post-restoration survey, photographs of all marine mammals hauled-out on the island shall be taken at an altitude greater than 300 m (984 ft) during the last departure flight from Northwest Seal Rock;

iv. The Society and/or its designees will forward the photographs to a biologist capable of discerning marine mammal species. The Society shall provide the data to us in the form of a report with a data table, any other significant observations related to marine mammals, and a report of restoration activities (see Reporting). The Society will make available the original photographs to NMFS or to other marine mammal experts for inspection and further analysis.

#### 7. Reporting Requirements

**Final Report:** The holder of this authorization is required to submit a draft monitoring report to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East West Highway, 13th Floor, Silver Spring, MD 20910; phone (301) 427-8401 no later than 90 days after the project is completed. The report must contain the following information:

a. A summary of the dates, times, and weather during all helicopter operations, restoration, and maintenance activities.

b. Species, number, location, and behavior of any marine mammals, observed throughout all monitoring activities.

c. An estimate of the number (by species) of marine mammals that are known to have been exposed to visual and acoustic stimuli associated with the helicopter operations, restoration, and maintenance activities.

d. A description of the implementation and effectiveness of the monitoring and mitigation measures of the IHA and full documentation of methods, results, and interpretation pertaining to all monitoring.

#### 8. Reporting Prohibited Take

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the authorization (if issued), such as an injury (Level A harassment), serious injury, or mortality (*e.g.*, vessel-strike, stampede, etc.), the Society shall immediately cease the specified activities and immediately report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301-427-8401 and the Assistant Western Regional Stranding Coordinator at (562) 980-3264.

The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.*, wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

The Society shall not resume its activities until we are able to review the circumstances of the prohibited take. We shall work with the Society to determine what is necessary to minimize the likelihood of further prohibited take and ensure Marine Mammal Protection Act compliance. The Society may not resume their activities until notified by us via letter, email, or telephone.

#### 9. Reporting an Injured or Dead Marine Mammal With an Unknown Cause of Death

In the event that the Society discovers an injured or dead marine mammal, and the lead visual observer determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.*, in less than a moderate state of decomposition as we describe in the next paragraph), the Society will immediately report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, at 301-427-8401 and the Assistant Western Regional Stranding Coordinator at (562) 980-3264. The report must include the same information identified in the paragraph above this section. Activities may continue while we review the circumstances of the incident. We will work with the Society to determine whether modifications in the activities are appropriate.

The report must include the same information identified in the paragraph above. Activities may continue while we review the circumstances of the incident. We will work with the Society to determine whether modifications in the activities are appropriate.

#### 10. Reporting an Injured or Dead Marine Mammal Not Related to the Society's Activities

In the event that the Society discovers an injured or dead marine mammal, and the lead visual observer determines that the injury or death is not associated with or related to the authorized activities (e.g., previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), the Society will report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, at 301-427-8401 and the Assistant Western Regional Stranding Coordinator at (562) 980-3264, within 24 hours of the discovery.

The Society's staff will provide photographs or video footage (if available) or other documentation of the stranded animal sighting to us.

11. This Authorization may be modified, suspended or withdrawn if the holder fails to abide by the conditions prescribed herein, or if the authorized taking is having a more than a negligible impact on the species or stock of affected marine mammals.

#### Request for Public Comments

NMFS requests comments on our analysis, the draft authorization, and any other aspect of this notice of proposed Authorization for the proposed activities. Please include any supporting data or literature citations with your comments to help inform our final decision on the Society's request for an Authorization.

Dated: October 20, 2015.

**Perry F. Gayaldo,**

*Deputy Director, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2015-27117 Filed 10-23-15; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

**ACTION:** Notice; public meeting.

**SUMMARY:** The Mid-Atlantic Fishery Management Council's (Council) Collaborative Research Committee will hold a public meeting.

**DATES:** The meeting will be held on Friday, Nov. 13, 2015, from 9 a.m. to 12 p.m.

**ADDRESSES:** The meeting will be held via webinar. Webinar connection details will be available at: <http://www.mafmc.org>.

**Council address:** Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331 or on their Web site at [www.mafmc.org](http://www.mafmc.org).

**FOR FURTHER INFORMATION CONTACT:** Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526-5255.

**SUPPLEMENTARY INFORMATION:** The Council has undertaken a short-term collaborative research initiative and intends to provide funding for several projects that address specific, Council-defined collaborative research topics pertaining to mid-Atlantic fisheries. The purpose of this Collaborative Research Committee meeting is to develop a list of 4-6 research priorities which will be used to guide the solicitation of proposals and selection of projects to receive funding. A detailed agenda and background documents will be made available on the Council's Web site ([www.mafmc.org](http://www.mafmc.org)) prior to the meeting.

#### Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526-5251, at least 5 days prior to the meeting date.

Dated: October 21, 2015.

**Tracey L. Thompson,**

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

[FR Doc. 2015-27132 Filed 10-23-15; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

RIN 0648-XE252

#### Takes of Marine Mammals Incidental to Specified Activities; Rehabilitation of the Jetty System at the Mouth of the Columbia River, Washington and Oregon

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

**ACTION:** Notice; receipt of application for letter of authorization; request for comments and information.

**SUMMARY:** NMFS has received a request from the U.S. Army Corps of Engineers,

Portland District (Corps) for authorization to take marine mammals incidental to the rehabilitation of the jetty system at the mouth of the Columbia River (MCR) including the North Jetty, South Jetty, and Jetty A. The Corps is requesting a Letter of Authorization (LOA) for pile installation and removal associated with construction of temporary offloading facilities at the North Jetty, South Jetty, and Jetty A over the course of 5 years; approximately September 2017 through August 2022. Pursuant to regulations implementing the Marine Mammal Protection Act (MMPA), NMFS is announcing receipt of the Corps' request for the development and implementation of regulations governing the incidental taking of marine mammals and inviting information, suggestions, and comments on the Corps' application and request.

**DATES:** Comments and information must be received no later than November 25, 2015.

**ADDRESSES:** Comments on the application should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to [ITP.Pauline@noaa.gov](mailto:ITP.Pauline@noaa.gov).

**Instructions:** NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted to the Internet at <http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm> without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

**FOR FURTHER INFORMATION CONTACT:** Robert Pauline, Office of Protected Resources, NMFS, (301) 427-8401.

**SUPPLEMENTARY INFORMATION:**

#### Availability

A copy of the Corps' application may be obtained by writing to the address specified above (see **ADDRESSES**), telephoning the contact listed above (see

**FOR FURTHER INFORMATION CONTACT**), or visiting the internet at: <http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm>

### Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified area, the incidental, but not intentional, taking of small numbers of marine mammals, providing that certain findings are made and the necessary prescriptions are established.

The incidental taking of small numbers of marine mammals may be allowed only if NMFS (through authority delegated by the Secretary) finds that the total taking by the specified activity during the specified time period will (i) have a negligible impact on the species or stock(s) and (ii) not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant). Further, the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such taking must be set forth, either in specific regulations or in an authorization.

The allowance of such incidental taking under section 101(a)(5)(A), by harassment (which is defined to include behavioral harassment and injury), serious injury, death, or a combination thereof, requires that regulations be promulgated for the specific activity. Subsequently, a Letter of Authorization may be issued pursuant to the prescriptions established in such regulations, providing that the level of taking will be consistent with the findings made for the total taking allowable under the specific regulations. Under section 101(a)(5)(D), NMFS may authorize such incidental taking by harassment only, for periods of not more than one year, pursuant to requirements and conditions contained within an IHA. The proposed incidental take authorization and establishment of prescriptions through either specific regulations or an IHA requires notice and opportunity for public comment.

NMFS has defined "negligible impact" in 50 CFR 216.103 as ". . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival." Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as: ". . . any act of

pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]."

Activities such as those described in the application (e.g., pile driving) may result in the disturbance of marine mammals through disruption of behavioral patterns

### Summary of Request

On February 13, 2015, NMFS received an application for a single multi-year project for the taking of marine mammals incidental to the rehabilitation of the North Jetty, South Jetty, and Jetty A at the MCR. NMFS issued an incidental harassment authorization (IHA) for the first year of the project on August 31, 2015 (80 FR 53777 September 8, 2015) allowing the take of specified marine mammals for work associated with the reconstruction of Jetty A only. The IHA is valid from May 1, 2016 through April 30, 2017. The Corps is seeking an LOA for this same project that would cover in-water work associated with continuation of Jetty A reconstruction as well as reconstruction of the North Jetty and South Jetty. The Corps has requested regulations to be effective for the period from approximately summer of 2017 through 2022. The Corps requested authorization to take marine mammals by Level B harassment only: Killer whale (*Orcinus orca*), Steller sea lion (*Eumatopius jubatus*), gray whale (*Eschrichtius robustus*), harbor porpoise (*Phocoena phocoena*), California sea lion (*Zalophus californianus*), and harbor seal (*Phoca vitulina richardii*).

### Specified Activities

The Corps is proposing to conduct monitoring actions, repairs, and rehabilitation of the three rubble-mound jetty structures at the MCR. The three structures are referred to as North Jetty, South Jetty, and Jetty A. Initial work on Jetty A will be covered by an IHA which has already been issued. The Corps is requesting a LOA for remaining pile repairs and removal actions at Jetty A, for pile installation and removal at North Jetty, and for pile installation and removal at South Jetty. Pile installation and removal activities are required as part of the construction of four temporary barge offloading facilities. These facilities combined will require up to 96 piles with a maximum

diameter of 24-inches and up to 373 sections of Z-piles to retain rock fill. They will be installed via vibratory installation. A full description of the activities proposed by the Corps is described in the application.

### Information Solicited

Interested persons may submit information, suggestions, and comments concerning the Corps' request (see **ADDRESSES**). All information, suggestions, and comments related to The Corps' request and NMFS' potential development and implementation of regulations governing the incidental taking of marine mammals by the Corps will be considered by NMFS in developing, if appropriate, regulations governing the issuance of letters of authorization.

Dated: October 20, 2015.

**Perry Gayaldo**,

*Deputy Director, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2015-27104 Filed 10-23-15; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### Caribbean Fishery Management Council (CFMC); Public Hearings

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

**ACTION:** Notice of public hearings on amendments to the U.S. Caribbean Reef fish, spiny lobster and corals and reef associated plants and invertebrates fishery management plans: timing of accountability measure-based closures.

**SUMMARY:** The CFMC is considering modifying the timing for the implementation of accountability measure based closures in the EEZ and specifying how often to revisit the modification. The Council is considering these management measures in order to ensure AM-based closures successfully achieve their conservation objective at the least cost to fishers and the fishing communities, consistent with National Standard 8 the Magnuson-Stevens Fishery Conservation and Management Act.

Following are the actions and management alternatives:

The Amendment consists of two actions:

Action 1: Modify the timing for the implementation of AM-based closures in the EEZ.

Alternative 1: No action. Continue AM-based closures resulting from an ACL overage beginning on December 31st of the closure year and extending backward in the year for the number of days necessary to achieve the required reduction in landings.

Alternative 2: Accountability measure-based closures resulting from an ACL overage will begin on September 30th of the closure year and would extend backward into the year for the number of days necessary to achieve the required reduction in landing. This closure start date would apply to all FMUs for each of Puerto Rico commercial and recreational sectors, St. Thomas/St. John, St. Croix, and Caribbean-wide. If for any FMU in any year, the number of days left in the year is not enough to achieve the required reduction in landings, then those additional days would be captured in the opposite direction.

Alternative 3: Accountability measure-based closures resulting from an ACL overage will begin on January 1st of the closure year and would extend forward into the year for the number of days necessary to achieve the required reduction in landing. This closure start date would apply to all FMUs for each of Puerto Rico commercial and recreational sectors, St. Thomas/St. John, St. Croix, and Caribbean-wide.

Alternative 4: Establish a fixed fishing closure start date for the implementation of AMs for each FMU (*i.e.*, species/species complex) by island/island group (Puerto Rico, St. Thomas/St. John, St. Croix, and Caribbean-wide). A different start date may be chosen for each FMU on each island/island group, but that start date would apply every year AMs need to be triggered for that FMU on that island. The start date will begin on the last day of the identified month and go backward towards the beginning of the year.

Alternative 4 Sub-alternatives:

Alternative 4(a): Closure to start the last day of the month with highest average landings.

Alternative 4(b): Closure to start the last day of the month with lowest average landing.

Alternative 4—Puerto Rico (Commercial):

Sub-alternative 4(a): Closure to start the last day of the month that has the highest landings based on the most recent three years of available landings data.

Sub-alternative 4(b): Closure to start the last day of the month with lowest landings based on the most recent three years of available landings data.

Alternative 4—Puerto Rico (Recreational):

Sub-alternative 4(a): Closure to start the last day of the month that has the highest landings based on the most recent three years of available landings data.

Sub-alternative 4(b): Closure to start the last day of the month with lowest landings based on the most recent three years of available landings data.

Alternative 4—St. Thomas/St. John, USVI (Commercial and Recreational combined):

Sub-alternative 4(a): Closure to start the last day of the month that has the highest landings based on the most recent three years of available landings data.

Sub-alternative 4(b): Closure to start the last day of the month with lowest landings based on the most recent three years of available landings data.

Alternative—Caribbean-Wide (Commercial and Recreational combined)

Sub-alternative 4(a): Closure to start the last day of the month that has the highest landings based on the most recent three years of available landings data (shortest closure time).

Sub-alternative 4(b): Closure to start the last day of the month with lowest landings based on the most recent three years of available landings data.

Action 2: Specify how often to revisit the approach selected in Action 1.

Alternative 1: No action. Do not specify how often the approach chosen should be revisited.

Alternative 2 (Preferred): Review the approach selected no longer than 2 years from implementation and every 2 years thereafter.

Alternative 3: Review the approach selected no longer than 5 years from implementation and every five years thereafter.

*Dates and Addresses:* The meetings will be held on the following dates and locations:

In the U.S. Virgin Islands:

November 16, 2015, 7 p.m.–10 p.m.—

The Buccaneer Hotel, Estate Shoys, Christiansted, St. Croix, USVI.

November 17, 2015, 7 p.m.–10 p.m.—

Windward Passage Hotel, Charlotte Amalie, St. Thomas, USVI.

In Puerto Rico:

November 23, 2015, 7 p.m.–10 p.m.—

Doubletree Hotel, De Diego Avenue, Santurce, PR.

November 24, 2015, 7 p.m.–10 p.m.—

Mayaguez Holiday Inn, 2701 Hostos Avenue, Mayagüez, Puerto Rico.

November 25, 2015, 2 p.m.–5 p.m.—

Holiday Inn Ponce & Tropical Casino, 3315 Ponce By Pass, Ponce,

Puerto Rico.

**FOR FURTHER INFORMATION CONTACT:**

Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918–1903, telephone (787) 766–5926.

**SUPPLEMENTARY INFORMATION:** Copy of the document, “Amendments to the U.S. Caribbean Reef fish, Spiny Lobster and Corals and Reef Associated Plants and Invertebrates Fishery Management Plans: Timing of Accountability Measure-Based Closures”, can be found at the CFMC Web page: [caribbeanfmc.com](http://caribbeanfmc.com).

Written comments can be sent to the Council not later than December 10, 2015, by regular mail to the address below, or via email to [graciela\\_cfmc@yahoo.com](mailto:graciela_cfmc@yahoo.com).

**Special Accommodations**

These meetings are physically accessible to people with disabilities. For more information or request for sign language interpretation and other auxiliary aids, please contact Mr. Miguel A. Rolón, Executive Director, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918–1903, telephone (787) 766–5926, at least 5 days prior to the meeting date.

Dated: October 21, 2015.

**Tracey L. Thompson,**

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

[FR Doc. 2015–27133 Filed 10–23–15; 8:45 am]

**BILLING CODE 3510–22–P**

**COMMISSION OF FINE ARTS**

**Notice of Meeting**

The next meeting of the U.S. Commission of Fine Arts is scheduled for 19 November 2015, at 9:00 a.m. in the Commission offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street NW., Washington, DC 20001–2728. Items of discussion may include buildings, parks and memorials.

Draft agendas and additional information regarding the Commission are available on our Web site: [www.cfa.gov](http://www.cfa.gov). Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing [cfastaff@cfa.gov](mailto:cfastaff@cfa.gov); or by calling 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.



Dated: 16 October 2015, in Washington, DC.

**Thomas Luebke,**  
Secretary.

[FR Doc. 2015-26859 Filed 10-23-15; 8:45 am]

BILLING CODE 6330-01-M

## COMMODITY FUTURES TRADING COMMISSION

### Agency Information Collection

#### Activities: Notice of Intent To Renew Collection: Clearing Member Risk Management

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice.

**SUMMARY:** The Commodity Futures Trading Commission (“Commission” or “CFTC”) is announcing an opportunity for public comment on the proposed renewal of a collection of certain information by the agency. Under the Paperwork Reduction Act (“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 2012, the Commission adopted final rules, which address risk management for cleared trades by futures commission merchants (“FCMs”), swap dealers (“SDs”), and major swap participants (“MSPs”) that are clearing members. This notice solicits comments on the obligation to maintain records related to clearing documentation between the customer and the customer’s clearing member.

**DATES:** Comments must be submitted on or before December 28, 2015.

**ADDRESSES:** You may submit comments, identified by “OMB Control No. 3038-0094,” by any of the following methods:

- The Agency’s Web site, at <http://comments.cftc.gov/>. Follow the instructions for submitting comments through the Web site.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.
- *Federal eRulemaking Portal:* <http://www.regulations.gov/>. Follow the instructions for submitting comments through the Portal.

Please submit your comments using only one method.

**FOR FURTHER INFORMATION CONTACT:** Christopher Hower, Special Counsel, Division of Clearing and Risk,

Commodity Futures Trading Commission, (202) 418-6703; email: [chower@cftc.gov](mailto:chower@cftc.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA, 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 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, the CFTC is publishing notice of the proposed collection of information listed below.

*Title:* Clearing Member Risk Management (OMB Control No. 3038-0094). This is a request for extension of a currently approved information collection.

*Abstract:* Section 3(b) of the Commodity Exchange Act (“Act”) provides that one of the purposes of the Act is to ensure the financial integrity of all transactions subject to the Act and to avoid systemic risk. Section 8a(5) authorizes the Commission to promulgate such regulations that it believes are reasonably necessary to effectuate any of the provisions or to accomplish any of the purposes of the Act. Risk management systems are critical to the avoidance of systemic risks.

Section 4s(j)(2) requires each SD and MSP to have risk management systems adequate for managing its business. Section 4s(j)(4) requires each SD and MSP to have internal systems and procedures to perform any of the functions set forth in Section 4s.

Section 4d requires FCMs to register with the Commission. It further requires FCMs to segregate customer funds. Section 4f requires FCMs to maintain certain levels of capital. Section 4g establishes reporting and recordkeeping requirements for FCMs. Pursuant to these provisions, the Commission adopted § 1.73 which applies to clearing members that are FCMs and § 23.609 which applies to clearing members that are SDs or MSPs. These provisions require these clearing members to have procedures to limit the financial risks they incur as a result of clearing trades and liquid resources to meet the obligations that arise. The regulations require clearing members to:

(1) Establish credit and market risk-based limits based on position size, order size, margin requirements, or similar factors;

(2) use automated means to screen orders for compliance with the risk-based limits;

(3) monitor for adherence to the risk-based limits intra-day and overnight;

(4) conduct stress tests of all positions in the proprietary account and all positions in any customer account that could pose material risk to the futures commission merchant at least once per week;

(5) evaluate its ability to meet initial margin requirements at least once per week;

(6) evaluate its ability to meet variation margin requirements in cash at least once per week;

(7) evaluate its ability to liquidate the positions it clears in an orderly manner, and estimate the cost of the liquidation at least once per month; and

(8) test all lines of credit at least once per quarter.

Each of these items has been observed by Commission staff as an element of an existing sound risk management program at an SD, MSP, or FCM. The Commission regulations require each clearing member to establish written procedures to comply with this regulation and to keep records documenting its compliance. The information collection obligations imposed by the regulations are necessary to implement certain provisions of the Act, including ensuring that registrants exercise effective risk management and for the efficient operation of trading venues among SDs, MSPs, and FCMs. 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.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to <http://www.cftc.gov>. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.<sup>1</sup>

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from <http://www.cftc.gov> that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

**Burden Statement:** The respondent burden for this collection is estimated to average 2 hours per response for an estimated annual burden of 504 hours per respondent. This estimate includes the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a federal agency.

**Respondents/Affected Entities:** Swap dealers, Major Swap Participants, and Futures Commission Merchants.

**Estimated number of respondents:** 239 (105 Swap Dealers and Major Swap Participants and 134 Futures Commission Merchants).

**Estimated number of responses:** 253.

**Estimated total annual burden on respondents:** 120,456 hours.

**Frequency of collection:** As needed.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: October 21, 2015.

**Robert N. Sidman,**

*Deputy Secretary of the Commission.*

[FR Doc. 2015-27164 Filed 10-23-15; 8:45 am]

**BILLING CODE P**

## CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2012-0034]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Baby Bouncers and Walker-Jumpers

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice.

**SUMMARY:** As required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Consumer Product Safety Commission ("CPSC" or "Commission") requests comments on a proposed extension of approval of a collection of information relating to certain children's articles known as baby-bouncers and walker-jumpers, approved previously under OMB Control No. 3041-0019. The Commission will consider all comments received in response to this notice before requesting an extension of this collection of information from the Office of Management and Budget ("OMB").

**DATES:** Submit written or electronic comments on the collection of information by December 28, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CPSC-2012-0034, by any of the following methods:

**Electronic Submissions:** Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through [www.regulations.gov](http://www.regulations.gov). The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

**Written Submissions:** Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

**Instructions:** All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

**Docket:** For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number CPSC-2012-0034, into the "Search" box, and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Robert H. Squibb, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504-7815, or by email to: [rsquibb@cpsc.gov](mailto:rsquibb@cpsc.gov).

**SUPPLEMENTARY INFORMATION:** CPSC seeks to renew the following currently approved collection of information:

**Title:** Ban of Certain Articles Known as Baby-Bouncers or Walker-Jumpers.

**OMB Number:** 3041-0019.

**Type of Review:** Renewal of collection.

**Frequency of Response:** On occasion.

**Affected Public:** Manufacturers and importers of baby-bouncers or walker-jumpers.

**Estimated Number of Respondents:** 33 firms that supply baby-bouncers or walker-jumpers to the United States market have been identified; there are approximately 4 new models per firm annually.

**Estimated Time per Response:** 30 minutes/model associated with labeling requirements and 1 hour/model associated with recordkeeping requirements.

**Total Estimated Annual Burden:** 132 hours on recordkeeping (33 firms × 1 hour × 4 models) and 66 hours for labeling (33 firms × ½ hour × 4 models) for a total annual burden of 198 hours per year.

**General Description of Collection:** Under 16 CFR 1500.18(a)(6), certain articles known as "baby-bouncers" and "walker-jumpers" which are intended to support very young children while sitting, bouncing, jumping, and/or reclining, are banned if they are designed in such a way that exposed parts present hazards such as amputation, crushing, laceration, fracture, hematoma, bruise, or other injury to fingers, toes, or other parts of the anatomy of young children. An exemption from the ban is provided at 16 CFR 1500.86(a)(4) if the products are designed to guard against or prevent those same injuries. Among other requirements, the regulations require manufacturers, including importers, to meet the collection of information requirements for labeling and recordkeeping requirements.

Products that are the subject of this information collection are distinguishable from the infant bouncer seats that are the subject of the

<sup>1</sup> 17 CFR 145.9.

Commission's recent proposed safety standard on infant bouncer seats at 80 FR 63168 (Oct. 19, 2015). Infant bouncer seats described in the Commission's proposed standard are intended to hold young infants that cannot sit up unassisted in a reclined position (approximately 0 to 6 months of age). Comments related to the Paperwork Reduction Act on the proposed safety standard for infant bouncer seats should be directed to the Office of Information and Regulatory Affairs, the Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

The products subject to this information collection are typically described as baby walkers, and allow the child to jump in place or assist with walking. Such products are intended for use with children that are beginning to develop leg strength to aid in learning to walk. Comments on the information collection requirements for these products should be submitted through the process outlined in the Addresses section above.

#### Request for Comments

The Commission solicits written comments from all interested persons about the proposed collection of information. The Commission specifically solicits information relevant to the following topics:

- Whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;
- Whether the estimated burden of the proposed collection of information is accurate;
- Whether the quality, utility, and clarity of the information to be collected could be enhanced; and
- Whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Dated: October 21, 2015.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

[FR Doc. 2015-27114 Filed 10-23-15; 8:45 am]

**BILLING CODE 6355-01-P**

## CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

### Proposed Information Collection; Comment Request

**AGENCY:** Corporation for National and Community Service.

**ACTION:** Notice.

**SUMMARY:** The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning the Operation AmeriCorps Evaluation. This two year evaluation seeks to assess the implementation of the new Operation AmeriCorps initiative, and to report on early results from the intended outcomes of each grantee's project. The evaluation will examine the extent to which multiple streams of national service are integrated and complement one another in each project; determine whether and how community capacity is being developed and sustained; and examine the Operation AmeriCorps grant making process to determine if this type of grant could be successfully used in future grants competitions. Researchers from CNCS will collect qualitative and quantitative data from grantees and their partners, AmeriCorps members, member supervisors, and program beneficiaries. Operation AmeriCorps grantees are required to participate in the evaluation as a condition of grant award.

Copies of the information collection request can be obtained by contacting the office listed in the Addresses section of this Notice.

**DATES:** Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by December 28, 2015.

**ADDRESSES:** You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* Corporation for National and Community Service, Office of Research and Evaluation; Attention Joseph Breems, Policy Analyst, Room 10902B; 1201 New York Avenue NW., Washington, DC, 20525.

(2) *By hand delivery or by courier to:* CNCS mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) *Electronically through* [www.regulations.gov](http://www.regulations.gov).

Individuals who use a telecommunications device for the deaf (TTY-TDD) may call 1-800-833-3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Joseph Breems, 202-606-6992, or by email at [jbreems@cns.gov](mailto:jbreems@cns.gov).

**SUPPLEMENTARY INFORMATION:** CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the efficient performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submissions of responses).

#### Background

This proposed two year evaluation seeks to assess the implementation of the new Operation AmeriCorps grant initiative, and to report on early results from the intended outcomes of each grantee's project. The evaluation will examine the extent to which multiple streams of national service are integrated and complement one another in each project; determine whether and how community capacity is being developed and sustained; and examine the Operation AmeriCorps grant making process to determine if this type of grant making process could be successful in the future.

**Current Action**

This is a new information collection request. Researchers from CNCS will collect qualitative and quantitative data from grantees and their partners, AmeriCorps members, member supervisors, and program beneficiaries. Quantitative data will be collected through a survey administered two times per year; qualitative information will be collected through interviews and focus groups.

*Type of Review:* New.

*Agency:* Corporation for National and Community Service.

*Title:* Operation AmeriCorps evaluation.  
*OMB Number:* None.  
*Agency Number:* None.  
*Affected Public:* Organizations receiving Operation AmeriCorps grants and their partners involved in implementing the grant, including: The legal applicant organization; the legal sub-applicant organization; key operating partners identified by the legal applicant and/or sub-applicant; peripheral supporting organizations identified by key operating partners and the legal applicant and/or sub-applicant; AmeriCorps members working on an Operation AmeriCorps project; member

supervisors working on an Operation AmeriCorps project; beneficiaries being served by an Operation AmeriCorps project.

*Total Respondents:* 170.

*Frequency:* Two times annually for survey; two times annually for grantee interviews, one time annually for other interviews and focus groups.

*Average Time per Response:* Averages 30 minutes for the survey; 90 minutes per interview; 60 minutes per focus group.

*Estimated Total Burden Hours:* 210 hours per year, or 12,600 minutes; see chart below.

**OPERATION AMERICORPS NATIONAL EVALUATION—PROJECTED BURDEN HOURS**

Instrument	Approx. time to administrate (hours)	Number of respondents	Number of administrations per respondent	Total burden (hours)
<b>YEAR 1:</b>				
Fall Interview .....	1	10	1	10
Survey .....	0.5	10	2	10
Spring Interview .....	1.5	80	1	120
Spring Focus Group .....	1	70	1	70
<i>Year 1 Total</i> .....		170		210
<b>YEAR 2:</b>				
Fall Interview .....	1	10	1	10
Survey .....	0.5	10	2	10
Spring Interview .....	1.5	80	1	120
Spring Focus Group .....	1	70	1	70
<i>Year 2 Total</i> .....		170		210
<b>Study Total</b> .....				420

*Total Burden Cost (capital/startup):* None.

*Total Burden Cost (operating/maintenance):* None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the

information collection request; they will also become a matter of public record.

Dated: October 20, 2015

**Mary Hyde,**

*Director of Research and Evaluation.*

[FR Doc. 2015-27155 Filed 10-23-15; 8:45 am]

**BILLING CODE 6050-28-P**

**DEPARTMENT OF ENERGY**

**Orders Granting Authority To Import and Export Natural Gas, To Import and Export Liquefied Natural Gas, To Vacate Authority, and Denying Request for Rehearing During September 2015**

	FE Docket Nos.
KOCH ENERGY SERVICES, LLC .....	15-115-NG
TALISMAN ENERGY USA INC .....	15-117-NG
EDF TRADING NORTH AMERICA, LLC .....	15-118-NG
AVISTA CORPORATION .....	15-116-NG
EDF TRADING NORTH AMERICA, LLC .....	15-119-LNG
EDF TRADING NORTH AMERICA, LLC .....	15-120-LNG
BARCLAYS BANK PLC .....	15-127-NG
JD IRVING, LIMITED .....	15-122-NG
FERUS NATURAL GAS FUELS LP .....	15-114-NG
RELIANT ENERGY NORTHEAST LLC .....	15-123-NG
OCCIDENTAL ENERGY MARKETING, INC .....	15-128-LNG
PUBLIC UTILITY DISTRICT NO. 1 OF CLARK COUNTY .....	15-129-NG
CONOCOPHILLIPS CANADA MARKETING & TRADING ULC .....	15-126-NG
TRANSALTA ENERGY MARKETING (U.S.) INC .....	15-132-NG
TRANSCANADA PIPELINES LIMITED .....	15-124-NG
JPMORGAN LNG CO .....	14-20-LNG
GAZ METRO SOLUTIONS TRANSPORT .....	15-131-LNG
TEXAS LNG BROWNSVILLE LLC .....	15-62-LNG

	FE Docket Nos.
CAMERON LNG, LLC .....	11-162-LNG
TEXAS LNG LLC .....	13-160-LNG
FREEMPORT LNG DEVELOPMENT, L.P. ....	15-103-LNG

**AGENCY:** Office of Fossil Energy, Department of Energy (DOE).

**ACTION:** Notice of orders.

**SUMMARY:** The Office of Fossil Energy (FE) of the Department of Energy gives notice that during September 2015, it issued orders granting authority to import and export natural gas, to import and export liquefied natural gas (LNG), to vacate authority, and denying request

for rehearing. These orders are summarized in the attached appendix and may be found on the FE Web site at <http://energy.gov/fe/downloads/listing-doe-fe-authorizations-orders-issued-2015>. They are also available for inspection and copying in the Office of Fossil Energy, Office of Oil and Gas Global Security and Supply, Docket Room 3E-033, Forrestal Building, 1000 Independence Avenue SW.,

Washington, DC 20585, (202) 586-9478. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on October 19, 2015.

**John A. Anderson,**

*Director, Office of Regulation and International Engagement, Office of Oil and Natural Gas.*

#### APPENDIX—DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS

3700 .....	15-115-NG .....	09/11/15	Koch Energy Services, LLC.	Order granting blanket authority to import/export natural gas from/to Canada.
3701 .....	15-117-NG .....	09/15/15	Talisman Energy USA Inc.	Order granting blanket authority to import/export natural gas from/to Canada.
3702 .....	15-118-NG .....	09/15/15	EDF Trading North America, LLC.	Order granting blanket authority to import/export natural gas from/to Canada/Mexico.
3703 .....	15-116-NG .....	09/15/15	Avista Corporation .....	Order granting blanket authority to import/export natural gas from/to Canada.
3704 .....	15-119-LNG .....	09/15/15	EDF Trading North America, LLC.	Order granting blanket authority to import/export LNG from/to Canada/Mexico by truck.
3705 .....	15-120-LNG .....	09/15/15	EDF Trading North America, LLC.	Order granting blanket authority to import LNG from various international sources by vessel and to export LNG to Canada/Mexico by vessel.
3706 .....	15-127-NG .....	09/17/15	Barclays Bank PLC .....	Order granting blanket authority to import natural gas from Canada.
3707 .....	15-122-NG .....	09/18/15	JD Irving, Limited .....	Order granting blanket authority to import natural gas from Canada.
3708 .....	15-114-NG .....	09/15/15	Ferus Natural Gas Fuels LP.	Order granting blanket authority to import/export natural gas from/to Canada.
3709 .....	15-123-NG .....	09/15/15	Reliant Energy Northeast LLC.	Order granting blanket authority to import/export natural gas from/to Canada.
3710 .....	15-128-LNG .....	09/15/15	Occidental Energy Marketing, Inc.	Order granting blanket authority to import LNG from various international sources by vessel.
3711 .....	15-129-NG .....	09/17/15	Public Utility District No. 1 of Clark County.	Order granting blanket authority to import/export natural gas from/to Canada.
3712 .....	15-126-NG .....	09/17/15	ConocoPhillips Canada Marketing & Trading ULC.	Order granting blanket authority to import/export natural gas from/to Canada.
3713 .....	15-132-NG .....	09/17/15	TransAlta Energy Marketing (U.S.) Inc.	Order granting blanket authority to import/export natural gas from/to Canada.
3714 .....	15-124-NG .....	09/17/15	TransCanada Pipelines Limited.	Order granting blanket authority to import/export natural gas from/to Canada.
3405-A .....	14-20-LNG .....	09/17/15	JPMorgan LNG Co .....	Order vacating blanket authority to import/export natural gas from/to Canada.
3715 .....	15-131-LNG .....	09/25/15	Gaz Metro Solutions Transport.	Order granting blanket authority to import LNG from Canada by truck.
3716 .....	15-62-LNG .....	09/24/15	Texas LNG Brownsville LLC.	Order granting long-term Multi-contract authority to export LNG by vessel from the proposed LNG Terminal at the Port of Brownsville, Texas to Free Trade Agreement Nations.
3391-B .....	11-162-LNG .....	09/24/15	Cameron LNG, LLC .....	Opinion and Order denying request for rehearing of Orders granting long-term Multi-contract authority to export LNG by vessel from the Cameron LNG Terminal in Cameron and Calcasieu Parishes, Louisiana to Non-free Trade Agreement Nations.
3443-A .....	13-160-LNG .....	09/24/17	Texas LNG LLC .....	Order vacating long-term authority Multi-contract authority to export LNG to Free Trade Agreement Nations, and Notice of Withdrawal of Application requesting long-term Multi-contract authority to export LNG to Non-free Trade Agreement Nations.

APPENDIX—DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS—Continued

3717 .....	15-103-LNG ....	09/25/15	Freeport LNG Develop- ment, L.P.	Order granting blanket authority to export pre- viously imported LNG by vessel.
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[FR Doc. 2015-27193 Filed 10-23-15; 8:45 am]  
**BILLING CODE 6450-01-P**

**DEPARTMENT OF ENERGY**

**Office of Energy Efficiency and Renewable Energy**

**Proposed Agency Information Collection**

**AGENCY:** Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of Energy (DOE) invites public comment on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995. 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, 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.

**DATES:** Comments regarding this proposed information collection must be received on or before November 10, 2015. If you anticipate difficulty in submitting comments within that period, contact the person listed in **ADDRESSES** as soon as possible.

**ADDRESSES:** Written comments may be sent to Mr. Chris Early, U.S. Department of Energy, Building Technologies Office, Mail Stop EE-5B, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585-0121 or by fax at 202-586-4617 or by email at *Chris.Early@ee.doe.gov*.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument and instructions should be directed to Mr. Chris Early, U.S.

Department of Energy, Building Technologies Office, Mail Stop EE-5B, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585-0121. *Chris.Early@ee.doe.gov*.

**SUPPLEMENTARY INFORMATION:** This information collection request contains: (1) OMB No. New; (2) Information Collection Request Title: Programs for Improving Energy Efficiency in Residential Buildings (3) Type of Request: New; (4) Purpose: The proposed collection will enable DOE to understand the universe of organizations participating in four voluntary programs: Zero Energy Ready Home Program, the Better Buildings Residential Network, the Home Energy Score, and the Home Performance with ENERGY STAR Program (HPwES). The DOE published a notice and request for comments for 60 days related to this current request to collect information on May 15, 2014 (79 FR 27867) and received no comments. That notice asked for comments for four voluntary programs at DOE, three of which are the same as for this current request for clearance and one is different. The DOE decided not to collect information for one of the four programs that was part of that May 15, 2014 request for comments, the Building America Program. The DOE, however, is adding the HPwES program to this current request for comments. The purpose of this 15 day notice and request for comments is to again request public comments on the three programs that were in the earlier 60 day notice and request for comments and also request comments on the HPwES program which was not included in that earlier 60 day FR notice. Through these four programs DOE encourages and assists the people and organizations that volunteer to participate in them to build and renovate new and existing houses to use less energy. The program partners who voluntarily participate in the programs consist of most of the actors in the home building industry including home owners, home builders, home builder tradesman and associations, home design professionals, students in architecture and related building construction industries, home energy raters, home energy auditors, home inspectors, building consultants, manufacturers of building products, professional trainers, utility companies, home building and manufacturing

industry associations, consumer and home building industry advocacy organizations, financial institutions, non-profit organizations, educational institutions, nonprofit organizations, energy program administrators and implementers, Home Performance with ENERGY STAR sponsors, state or local government energy offices or agencies, clean energy non-profits with existing residential energy programs and other organizations who believe peer sharing will help them improve their effectiveness in encouraging homeowners to complete energy upgrades. DOE proposes to collect information about the participants such as their names and addresses, their evaluations of training they received about the programs, descriptions of their qualifications to conduct training for the programs, their plans to get people to participate in the programs, their certifications describing how they can assess homes, estimates of how many homes they can get to participate in the programs, and information about the homes. The collected information will help DOE understand the participating partners' activities and progress toward achieving scheduled milestones enabling DOE to make decisions about the best way to run the programs and respond to partners' needs to improve their operations and actions to lower energy consumption. The portion of the HPwES Program for which DOE is requesting comments was run by EPA. The operation of part of the HPwES program is to be transferred to the DOE from the Environmental Protection Agency (EPA). The DOE intends to operate HPwES substantially similarly to the way EPA operates the program. The difference in estimates of numbers of responses, number of respondents, burden hours, and costs to respond between the HPwES that was approved by OMB for EPA and the one requested to be approved by DOE are minor. The OMB did give the EPA clearance for collection of information in the HPwES program on August 14, 2014. OMB gave it the ICR Control Number 2060-0586. EPA did not receive any comments in either the 30 or 60 day **Federal Register** Notices for that collection of information; (5) Annual Estimated Number of Respondents: 11,585. (6) Annual Estimated Number of Total Responses: 46,909. (7) Annual Estimated Number of Burden Hours:

22,926. (8) Annual Estimated Reporting and Recordkeeping Cost Burden: zero dollars. DOE estimates that there are no additional costs to respondents associated with the surveys other than the costs associated with the burden hours.

**Statutory Authority:** The U.S. Code, Title 42, Chapter 149, Subchapter IX, Part A, Section 16191—Energy Efficiency.

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

**Roland J. Risser,**

*Director, Building Technologies Office,  
Energy Efficiency and Renewable Energy.*

[FR Doc. 2015-27202 Filed 10-23-15; 8:45 am]

**BILLING CODE 6450-01-P**

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-9936-18—Region 6]

### Clean Air Act Operating Permit Program; Petition for Objection to State Operating Permits for Shell Chemical LP Deer Park Chemical Plant and Shell Oil Company Deer Park Refinery in Texas

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of final action.

**SUMMARY:** Pursuant to Clean Air Act (CAA) Section 505(b)(2) and 40 CFR 70.8(d), the EPA Administrator signed an Order, dated September 24, 2015, granting in part and denying in part two petitions asking EPA to object to operating permits issued by the Texas Commission on Environmental Quality for Shell Chemical LP's Deer Park Chemical Plant and Shell Oil Company's Deer Park Refinery (Title V operating permit numbers O1668 and O1669). The EPA's September 24, 2015 Order responds to the two petitions, dated May 19, 2014, submitted by the Environmental Integrity Project (EIP), Sierra Club, and Air Alliance Houston. Sections 307(b) and 505(b)(2) of the CAA provide that a petitioner may ask for judicial review by the United States Court of Appeals for the appropriate circuit of those portions of the Order that deny issues raised in the petition. Any petition for review shall be filed within 60 days from the date this notice appears in the **Federal Register**, pursuant to section 307(b) of the CAA.

**ADDRESSES:** You may review copies of the final Order, the petition, and other supporting information at EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.

EPA requests that if at all possible, you contact the individual listed in the

**FOR FURTHER INFORMATION CONTACT** section to view copies of the final Order, petitions, and other supporting information. You may view the hard copies Monday through Friday, from 9:00 a.m. to 3:00 p.m., excluding Federal holidays. If you wish to examine these documents, you should make an appointment at least 24 hours before the visiting day. Additionally, the final September 24, 2015 Order is available electronically at: <http://www2.epa.gov/title-v-operating-permits/order-responding-2014-petition-requesting-administrator-object-deer-park>.

**FOR FURTHER INFORMATION CONTACT:** Aimee Wilson at (214) 665-7596, email address: [wilson.aimee@epa.gov](mailto:wilson.aimee@epa.gov) or the above EPA, Region 6 address.

**SUPPLEMENTARY INFORMATION:** The CAA affords EPA a 45-day period to review, and object, as appropriate, to a title V operating permit proposed by a state permitting authority. Section 505(b)(2) of the CAA authorizes any person to petition the EPA Administrator, within 60 days after the expiration of this review period, to object to a title V operating permit if EPA has not done so. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise such objections during the comment period or unless the grounds for the objection arose after this period.

The Petitioners maintain that the Shell Deer Park title V operating permits are inconsistent with the Act based on the following contentions: (1) The proposed permits' incorporation by reference of minor NSR authorizations fails to assure compliance; (2) The proposed permits' incorporation by reference of permits by rule fails to assure compliance; (3) The proposed permits fail to require monitoring, recordkeeping, and reporting sufficient to assure compliance with applicable requirements; (4) The proposed permit for the Deer Park Refinery impermissibly uses the permit shield provisions; (5) The proposed permits fail to require Shell to obtain SIP-approved authorizations for qualified facilities changes; (6) The proposed permit for the Chemical Plant fails to address Shell's non-compliance with 30 Texas Administrative Code section 116.116(d), which requires PBRs for previously permitted facilities to be incorporated into existing permits on renewal or amendment; (7) The Executive Director's revision to draft permits' special condition 28 in O1668

and special condition 29 in O1669 are improper; and (8) The proposed permits must clarify that credible evidence may be used by citizens to enforce the terms and conditions of the permits. The claims are described in detail in Section IV of the Order.

Pursuant to sections 505(b) and 505(e) of the Clean Air Act (42 U.S.C. 7661d(b) and (e)) and 40 CFR 70.7(g) and 70.8(d), the Texas Commission on Environmental Quality (TCEQ) has 90 days from the receipt of the Administrator's order to resolve the objections identified in Claims 2., 3.B., 3.C., and 6. of the Order and submit a proposed determination or termination, modification, or revocation and reissuance of the Shell Deer Park title V permits in accordance with EPA's objections. The Order issued on September 24, 2015 responds to the Petitions and explains the basis for EPA's decisions.

Dated: October 15, 2015.

**Samuel Coleman,**

*Acting Regional Administrator, Region 6.*

[FR Doc. 2015-27161 Filed 10-23-15; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[FRL 9936-15-0A]

### Notification of a Public Teleconference of the Clean Air Scientific Advisory Committee Secondary National Ambient Air Quality Standards Review Panel for Oxides of Nitrogen and Sulfur

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public teleconference of the Clean Air Scientific Advisory Committee (CASAC) Secondary National Ambient Air Quality Standards (NAAQS) Review Panel for Oxides of Nitrogen and Sulfur to peer review EPA's *Integrated Review Plan (IRP) for the Secondary (welfare-based) National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur*.

**DATES:** The CASAC Secondary NAAQS Review Panel for Oxides of Nitrogen and Sulfur will hold a teleconference on Tuesday December 1, 2015 from 1:00 p.m. to 5:00 p.m. (Eastern Standard Time).

*Location:* The public teleconference will take place by telephone only.

**FOR FURTHER INFORMATION CONTACT:** Any member of the public wishing to obtain information concerning the public meeting may contact Dr. Sue Shallal, Designated Federal Officer (DFO), EPA Science Advisory Board Staff Office (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; by telephone/voice mail at (202) 564-2057 or at [shallal.suhair@epa.gov](mailto:shallal.suhair@epa.gov). General information about the CASAC, as well as any updates concerning the teleconference announced in this notice, may be found on the EPA Web site at <http://www.epa.gov/casac>.

**SUPPLEMENTARY INFORMATION:** The CASAC was established pursuant to the Clean Air Act (CAA) Amendments of 1977, codified at 42 U.S.C. 7409(d)(2), in part to review air quality criteria and NAAQS and recommend any new NAAQS and revisions of existing criteria and NAAQS as may be appropriate. The CASAC is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2, Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the NAAQS for the six "criteria" air pollutants, including oxides of nitrogen and oxides of sulfur. EPA is currently reviewing the secondary (welfare-based) ambient air quality standards for oxides of nitrogen and sulfur and has requested CASAC advice. Accordingly, the SAB Staff Office solicited nominations for the CASAC Secondary NAAQS Review Panel for Oxides of Nitrogen and Sulfur on March 27, 2014 (79 FR 17147-17149). Membership of the Panel is listed at <http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubcommittees/Secondary%20NAAQS%20Review%20Panel%20for%20Oxides%20of%20Nitrogen%20and%20Sulfur>. EPA will develop several documents in support of its review of the secondary (welfare-based) NAAQS for oxides of nitrogen and sulfur, drafts of which will be subject to review by the CASAC panel. These documents include the Integrated Review Plan (IRP) for the secondary NAAQS for oxides of nitrogen and sulfur, the Integrated Science Assessment (ISA) for Oxides of Nitrogen and Sulfur—Ecological Criteria; a Risk and Exposure Assessment (REA), as warranted; and the Policy Assessment (PA).

Pursuant to FACA and EPA policy, notice is hereby given that the CASAC Secondary National Ambient Air Quality Standards Review Panel for Oxides of Nitrogen and Sulfur will hold a public teleconference to peer review

EPA's *Integrated Review Plan (IRP) for the Secondary (welfare-based) National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur*. The CASAC Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

**Technical Contacts:** Any technical questions concerning the *Integrated Review Plan (IRP) for the Secondary (welfare-based) National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur* should be directed to Ms. Ginger Tennant ([tennant.ginger@epa.gov](mailto:tennant.ginger@epa.gov)), EPA Office Air Quality Planning and Standards.

**Availability of Meeting Materials:** Prior to the teleconference, the review documents, agenda and other materials will be accessible through the calendar link on the blue navigation bar at <http://www.epa.gov/casac/>.

**Procedures for Providing Public Input:** Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit comments for a federal advisory committee to consider as it develops advice for EPA. Interested members of the public may submit relevant written or oral information on the topic of this advisory activity, and/or the group conducting the activity, for the CASAC to consider during the advisory process. Input from the public to the CASAC will have the most impact if it provides specific scientific or technical information or analysis for CASAC panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the DFO directly.

**Oral Statements:** In general, individuals or groups requesting an oral presentation at a public teleconference will be limited to three minutes. Each person making an oral statement should consider providing written comments as well as their oral statement so that the points presented orally can be expanded upon in writing. Interested parties should contact Dr. Sue Shallal, DFO, in writing (preferably via email) at the contact information noted above by November 17, 2015 to be placed on the list of public speakers.

**Written Statements:** Written statements should be supplied to the DFO via email at the contact information noted above by November 17, 2015 so that the information may be made available to the Panel members for their consideration. It is the SAB Staff Office general policy to post written comments on the Web page for the advisory meeting or teleconference. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the CASAC Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

**Accessibility:** For information on access or services for individuals with disabilities, please contact Dr. Sue Shallal at the contact information provided above. To request accommodation of a disability, please contact Dr. Shallal preferably at least ten days prior to the teleconference to give EPA as much time as possible to process your request.

Dated: October 15, 2015.

**Thomas H. Brennan,**  
Deputy Director, EPA Science Advisory Staff Office.

[FR Doc. 2015-27160 Filed 10-23-15; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-9936-19-OA]

### Performance Partnership Grants

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This action adds the Beaches Environmental Assessment and Coastal Health (BEACH) Act grant program to the list of the Environmental Protection Agency's (EPA) environmental grant programs eligible for inclusion in Performance Partnership Grants (PPGs).

**FOR FURTHER INFORMATION CONTACT:** Reynold Meni, Office of Congressional and Intergovernmental Relations, Office of the Administrator (Mail Code 1301), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-3669; fax number: (202) 501-1540; email address: [meni.reynold@epa.gov](mailto:meni.reynold@epa.gov).

**SUPPLEMENTARY INFORMATION:** The Omnibus Consolidated Rescissions and Appropriations Act of 1996 (Pub. L.

104–134) and the Department of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act of 1998 (Pub. L. 105–65) authorize EPA to combine categorical grant funds appropriated in EPA's State and Tribal Assistance Grant (STAG) account and award the funds as PPGs. Public Law 104–134 states, in relevant part, that: “the Administrator is authorized to make grants annually from funds appropriated under this heading, subject to such terms and conditions as the Administrator shall establish, to any State or federally recognized Indian tribe for multimedia or single media pollution prevention, control and abatement and related environmental activities at the request of the Governor or other appropriate State official or the tribe.”

Public Law 105–65 amended the PPG authority by authorizing “interstate agencies, tribal consortia, and air pollution control agencies” to receive PPGs. Pursuant to the authority granted in Public Law 104–134 and Public Law 105–65, EPA promulgated PPG regulations in January of 2001 as part of the Agency's revision of 40 CFR part 35, the rules governing categorical environmental program grants. The regulation at 40 CFR 35.133(b) states that: “The Administrator may, in guidance or regulation, describe subsequent additions, deletions, or changes to the list of environmental programs eligible for inclusion in Performance Partnership Grants.”

EPA is authorized under Section 406 of the Clean Water Act (CWA), as amended by the Beaches Environmental Assessment and Coastal Health (BEACH) Act (Pub. L. 106–284), to award program development and implementation grants to eligible states, territories, tribes, and local governments to support microbiological monitoring and public notification of the potential for exposure to disease-causing microorganisms in coastal recreation waters, including the Great Lakes. The BEACH Act grant program is funded in the same line item that funds categorical grants for “multimedia or single media pollution prevention, control and abatement and related environmental activities” and, therefore, this grant program is eligible for inclusion in PPGs. This notice is made pursuant to 40 CFR 35.133(b), to inform entities eligible to receive PPGs that the program listed above may be included in a PPG subject to any limitations herein defined. Hereafter, BEACH Act grants are eligible for inclusion in PPGs and may be included in a PPG at the request of the appropriate official of an eligible

entity, subject to EPA's regulations at 2 CFR part 200 and 2 CFR part 1500 and 40 CFR 35.001–35.138 and 35.500–35.538. The authority to issue this **Federal Register** notice has been delegated to the Deputy Associate Administrator for Intergovernmental Relations.

Dated: October 19, 2015.

**Mark W. Rupp,**

*Deputy Associate Administrator for Intergovernmental Relations.*

[FR Doc. 2015–27162 Filed 10–23–15; 8:45 am]

**BILLING CODE 6560–50–P**

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## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0601 and 3060–0594]

### Information Collections Being Reviewed by the Federal Communications Commission Under Delegated Authority

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

**DATES:** Written PRA comments should be submitted on or before December 28, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Cathy Williams, FCC, via email [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Cathy.Williams@fcc.gov](mailto:Cathy.Williams@fcc.gov).

**FOR FURTHER INFORMATION CONTACT:** For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

#### SUPPLEMENTARY INFORMATION:

*OMB Control Number:* 3060–0601.

*Title:* Setting Maximum Initiated Permitted Rates for Regulated Cable Services, FCC Form 1200.

*Form Number:* FCC Form 1200.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit entities; State, Local, or Tribal Government.

*Number of Respondents and Responses:* 100 respondents; 50 responses.

*Estimated Hours per Response:* 2–10 hours.

*Frequency of Response:* One time and annual reporting requirements; Third party disclosure requirement.

*Total Annual Burden:* 800 hours.

*Total Annual Costs:* \$62,500.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 623 of the Communications Act of 1934, as amended.

*Nature and Extent of Confidentiality:* There is no need for confidentiality with this collection of information.

*Privacy Impact Assessment:* No impact(s).

*Needs and Uses:* The Cable Television Consumer Protection and Competition Act of 1992 required the Commission to prescribe rules and regulations for determining reasonable rates for basic tier cable service and to establish criteria for identifying unreasonable rates for cable programming services and associated equipment. FCC Form 1200 is used by cable operators to justify the reasonableness of rates in effect on or after May 15, 1994. Cable operators submit this form to local franchising authorities (“LFAs”) or the Commission, in situations where the Commission has assumed jurisdiction. FCC Form 1200 also is filed with the Commission when responding to a complaint filed with the Commission about cable programming service rates and associated equipment.

*OMB Control Number:* 3060–0594.



*Title:* Cost of Service Filing for Regulated Cable Services, FCC Form 1220.

*Form Number:* FCC Form 1220.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit entities; State, Local, or Tribal Government.

*Number of Respondents and Responses:* 20 respondents; 10 responses.

*Estimated Hours per Response:* 4–80 hours.

*Frequency of Response:* On occasion and annual reporting requirements; Third party disclosure requirement.

*Total Annual Burden:* 1,220 hours.

*Total Annual Costs:* \$100,000.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 154(i) and 623 of the Communications Act of 1934, as amended.

*Nature and Extent Confidentiality:* There is no need for confidentiality with this collection of information.

*Privacy Impact Assessment:* No impact(s).

*Needs and Uses:* The Cable Television Consumer Protection and Competition Act of 1992 required the Commission to prescribe rules and regulations for determining reasonable rates for basic tier cable service and to establish criteria for identifying unreasonable rates for cable programming services and associated equipment. FCC Form 1220 is used by cable operators to demonstrate their costs of providing cable service in order to justify rates above levels determined under the Commission's benchmark methodology. Cable operators submit this form to local franchising authorities ("LFAs") or the Commission (in situations where the Commission has assumed jurisdiction) only when justifying rates based on cost of service.

Federal Communications Commission.

**Gloria J. Miles,**

*Federal Register Liaison Officer, Office of the Secretary.*

[FR Doc. 2015–27105 Filed 10–23–15; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0837]

### Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

**DATES:** Written PRA comments should be submitted on or before December 28, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Cathy Williams, FCC, via email [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Cathy.Williams@fcc.gov](mailto:Cathy.Williams@fcc.gov).

**FOR FURTHER INFORMATION CONTACT:** For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

#### SUPPLEMENTARY INFORMATION:

*OMB Control Number:* 3060–0837.

*Title:* FCC Form 2100, Application for Media Bureau Audio and Video Service Authorization, Schedule B.

*Form Number:* FCC Form 2100, Schedule B.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit entities; Not-for-profit institutions.

*Number of Respondents/Responses:* 300 respondents; 300 responses.

*Estimated Time per Response:* 2 hours.

*Frequency of Response:* On occasion reporting requirement.

*Total Annual Burden:* 600 hours.

*Total Annual Costs:* \$133,800.

*Nature of Response:* Required to obtain or retain benefits. Statutory authority for this collection of information is contained in Sections 154(i), 303 and 308 of the Communications Act of 1934, as amended.

*Nature and Extent of Confidentiality:* There is no need for confidentiality with this information collection.

*Privacy Act Impact Assessment:* No impact(s).

*Needs and Uses:* Licensees and permittees of DTV broadcast stations are required to file FCC Form 302–DTV to obtain a new or modified station license, and/or to notify the Commission of certain changes in the licensed facilities of these stations. FCC staff use the data to confirm that the station has been built to terms specified in the outstanding construction permit, and to update FCC station files. Staff extracted the data from FCC Form 2100, Schedule B, for inclusion in the subsequent license to operate the station.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2015–27138 Filed 10–23–15; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

[DA 15–1075]

### Notice of Debarment; Federal Lifeline Universal Service Support Mechanism

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice.

**SUMMARY:** The Enforcement Bureau (Bureau) gives notice of Wes Yui Chew's debarment from the federal Lifeline universal service support mechanism (Lifeline program) for a period of three years. During this debarment period, Mr. Chew is prohibited from participating in activities associated with or related to the Lifeline program, including the receipt of funds or discounted services through the Lifeline program, or consulting with, assisting, or advising applicants or service providers regarding the Lifeline program.

**DATES:** Debarment commences on the date Mr. Chew receives the debarment

letter or October 26, 2015, whichever comes first, for a period of three years.

**FOR FURTHER INFORMATION CONTACT:**

Celia Lewis, Paralegal Specialist, Federal Communications Commission, Enforcement Bureau, Investigations and Hearings Division, Room 4-A422, 445 12th Street SW., Washington, DC 20554. Celia Lewis may be contacted by phone at (202) 418-7456 or email at [Celia.Lewis@fcc.gov](mailto:Celia.Lewis@fcc.gov). If Ms. Lewis is unavailable, you may contact Mr. Kalun Lee, Deputy Chief, Investigations and Hearings Division, by telephone at (202) 418-0796 and by email at [Kalun.Lee@fcc.gov](mailto:Kalun.Lee@fcc.gov).

**SUPPLEMENTARY INFORMATION:** The Bureau debars Mr. Chew for a period of three years pursuant to 47 CFR 54.8 and 0.111(a)(14). Mr. Chew's conviction for money laundering in violation of 18 U.S.C. 1957(a), in connection with fraudulent claims against the Lifeline program is the basis for this debarment. Attached is the Notice of Debarment, DA 15-1075, which was mailed to Mr. Chew and released on September 25, 2015. The complete text of the Notice of Debarment is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portal II, 445 12th Street SW., Room CY-A257, Washington, DC 20554. In addition, the complete text is available on the FCC's Web site at <http://www.fcc.gov>.

Federal Communications Commission.

**Jeffrey J. Gee,**

*Chief, Investigations and Hearings Division, Enforcement Bureau.*

September 25, 2015

**DA 15-1075**

**SENT VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED**

Mr. Wes Yui Chew

c/o Daniel G. Webber, Jr.

Ryan Whaley Coldiron Shandy PLLC

119 N. Robinson Avenue, Suite 900

Oklahoma City, OK 73102

**Re: Notice of Debarment, File No. EB-IHD-15-00019046**

Dear Mr. Chew:

The Federal Communications Commission (Commission) hereby notifies you that, pursuant to section 54.8 of the Commission's rules, you are prohibited from participating in activities associated with or related to the federal low-income support mechanism (Lifeline program) for three years from either the date of your receipt of this Notice of Debarment or of its publication in the Federal Register,

whichever comes first (Debarment Date).<sup>1</sup>

On May 26, 2015, the Commission's Enforcement Bureau (Bureau) sent you a Notice of suspension and initiation of debarment proceeding (*Notice of Suspension*) that was published in the **Federal Register** on June 18, 2015.<sup>2</sup> The *Notice of Suspension* suspended you from participating in any activities associated with or related to the Lifeline program, including receiving funds or discounted services through the Lifeline program, or consulting with, assisting, or advising applicants or service providers regarding the Lifeline program.<sup>3</sup> It also described the basis for initiating debarment proceedings against you, the applicable debarment procedures, and the effect of debarment.

As discussed in the *Notice of Suspension*, on June 12, 2014, you were convicted of money laundering in violation of 18 U.S.C. 1957(a), in connection with fraudulent claims against the federal Lifeline program.<sup>4</sup> You were the sole owner and president of Icon Telecom, Inc. (Icon), a participant in the Lifeline program from July 2011 until September 2013.<sup>5</sup> Specifically, you pled guilty to one count of money laundering for transferring \$20,455,829.10 from an Icon bank account to a personal bank account, despite knowing that Icon had thousands fewer customers than it had reported to the Commission.<sup>6</sup> Pursuant

<sup>1</sup> 47 CFR 54.8 (e), (g); 47 CFR 0.111 (delegating to the Bureau authority to resolve universal service suspension and debarment proceedings). In 2007, the Commission extended the debarment rules to apply to all federal universal service support mechanisms, including the Lifeline program. See *Comprehensive Review of the Universal Service Fund Management, Administration, & Oversight*, Report and Order, 22 FCC Rcd 16372, 16410-12 (2007) (*Program Management Order*) (renumbering section 54.521 of the universal service debarment rules as section 54.8 and amending subsections (a)(1), (a)(5), (c), (d), (e)(2)(i), (e)(3), (e)(4), and (g)).

<sup>2</sup> Letter from Jeffrey J. Gee, Chief, Investigations and Hearings Division, FCC Enforcement Bureau, to Wes Yui Chew, Notice of suspension and initiation of debarment proceeding, 30 FCC Rcd 5006 (Enf. Bur. 2015); 80 FR 34906-01 (June 18, 2015).

<sup>3</sup> 47 CFR 54.8(a)(1), (d).

<sup>4</sup> Any further reference in this letter to "your conviction" refers to your guilty plea and subsequent sentencing in *United States v. Chew*, Criminal Docket No. 5:14-cr-00170-D, Plea Agreement (W.D. Okla. filed June 12, 2014) (*Plea Agreement*). See also *Lifeline & Link Up Reform & Modernization*, WC Docket No. 11-42, CC Docket No. 96-45, WC Docket No. 03-109, Report and Order and Further Notice of Proposed Rulemaking, 27 FCC Rcd 6656 (2012) (*Lifeline Reform Order*).

<sup>5</sup> *United States v. Chew*, Criminal Docket No. 5:14-cv-00170-D, Information at 4 (W.D. Okla. filed June 3, 2014).

<sup>6</sup> *Id.* at 7-8; Plea Agreement at 2; see also United States Attorney's Office, western District of Oklahoma, Press Release, Icon Telecom and Its Owner Plead Guilty And Agree To Forfeit More Than \$27 Million In Connection With Federal

to section 54.8(c) of the Commission's rules, your conviction of criminal conduct in connection with the Lifeline program is the basis for this debarment.<sup>7</sup>

In accordance with the Commission's debarment rules, you were required to file with the Commission any opposition to your suspension or its scope, or to your proposed debarment or its scope, no later than 30 calendar days from either the date of your receipt of the *Notice of Suspension* or of its publication in the Federal Register, whichever date occurred first.<sup>8</sup> The Commission received no opposition from you.

For the foregoing reasons, you are debarred from involvement with the Lifeline program for three years from the Debarment Date.<sup>9</sup> During this debarment period, you are excluded from participating in any activities associated with or related to the Lifeline program, including the receipt of funds or discounted services through the Lifeline program, or consulting with, assisting, or advising applicants or service providers regarding the Lifeline program.<sup>10</sup>

Sincerely yours,

Jeffrey J. Gee

*Chief, Investigations and Hearings Division, Enforcement Bureau*

cc: Johnnay Schrieber, Universal Service Administrative Company (via email), Rashann Duvall, Universal Service Administrative Company (via email), Chris M. Stevens, United States Attorney's Office, Western District of Oklahoma (via email), Scott E. Williams, United States Attorney's Office, Western District of Oklahoma (via email)

[FR Doc. 2015-27076 Filed 10-23-15; 8:45 am]

**BILLING CODE 6712-01-P**

**FEDERAL DEPOSIT INSURANCE CORPORATION**

**Notice to All Interested Parties of the Termination of the Receivership of 10360, Cortez Community Bank Brooksville, Florida**

NOTICE IS HEREBY GIVEN that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for Cortez Community Bank, Brooksville, Florida ("the Receiver") intends to terminate its receivership for said institution. The

Wireless Telephone Subsidy Program, June 12, 2014, available at <http://www.justice.gov/usao-wd-ok/pr/icon-telecom-and-its-owner-plead-guilty-and-agree-forfeit-more-27-million-connection>.

<sup>7</sup> 47 CFR 54.8(c).

<sup>8</sup> *Id.* § 54.8 (e)(3)-(4). Any opposition had to be filed no later than July 1, 2015.

<sup>9</sup> 47 CFR 54.8(g).

<sup>10</sup> 47 CFR 54.8(a)(1), (d), (g).

FDIC was appointed receiver of Cortez Community Bank on April 29, 2011. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 32.1, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: October 20, 2015.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2015-27084 Filed 10-23-15; 8:45 am]

**BILLING CODE 6714-01-P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Notice to All Interested Parties of the Termination of the Receivership of 4556 Meritor Savings Bank Philadelphia, Pennsylvania

NOTICE IS HEREBY GIVEN that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for Meritor Savings Bank, Philadelphia, Pennsylvania ("the Receiver") intends to terminate its receivership for said institution. The FDIC was appointed receiver of Meritor Savings Bank on December 11, 1992. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the

termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: October 20, 2015.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2015-27085 Filed 10-23-15; 8:45 am]

**BILLING CODE 6714-01-P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 11:15 a.m. on Thursday, October 22, 2015, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

In calling the meeting, the Board determined, on motion of

Vice Chairman Thomas M. Hoenig, seconded by Director

Thomas J. Curry (Comptroller of the Currency), concurred in by Director Richard Cordray (Director, Consumer Financial Protection Bureau), and Chairman Martin J. Gruenberg, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

Dated: October 22, 2015.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2015-27295 Filed 10-22-15; 4:15 pm]

**BILLING CODE 6714-01-P**

## FEDERAL ELECTION COMMISSION

### Sunshine Act Meetings

**AGENCY:** Federal Election Commission.

**DATE AND TIME:** *Thursday, October 29, 2015 at 10:00 a.m.*

**PLACE:** 999 E Street NW., Washington, DC (ninth floor).

**STATUS:** This meeting will be open to the public.

**ITEMS TO BE DISCUSSED:**

Correction and Approval of Minutes for

September 17 and October 1, 2015

Demonstration of FEC Web site

Redesign, Beta Version

Draft Advisory Opinion 2015-08:

Repledge

Draft Advisory Opinion 2015-09: Senate

Majority PAC and House Majority

PAC

Draft Advisory Opinion 2015-10: 21st

Century Fox

Rulemaking Priorities and Proposals

Notice of Proposed Rulemaking on

Reporting Multistate Independent

Expenditures and Electioneering

Communications in Presidential

Primary Elections

Commission Documents/Public

Disclosure Policies

Proposed Final Audit Report on the

Committee for Charlotte/Charlotte

DNC Host Committee

Proposed Amendment to Directive 52—

Technical and Conforming Authority

Management and Administrative

Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary and Clerk, at (202) 694-1040, at least 72 hours prior to the meeting date.

**PERSON TO CONTACT FOR INFORMATION:**

Judith Ingram, Press Officer, Telephone:

(202) 694-1220.

**Shawn Woodhead Werth,**

*Secretary and Clerk of the Commission.*

[FR Doc. 2015-27336 Filed 10-22-15; 4:15 pm]

**BILLING CODE 6715-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10280]

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by December 28, 2015.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:****Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

*CMS-10280 Home Health Change of Care Notice (HHCCN)*

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Home Health Change of Care Notice (HHCCN); *Use:* The Home Health Change of Care Notice (HHCCN) is used to notify original Medicare beneficiaries receiving home health care benefits of plan of care changes. Home health agencies (HHAs) must provide the HHCCN whenever they reduce or terminate a beneficiary's home health services due to physician/provider orders or limitation of the HHA in providing the specific service. Notification is required for covered and non-covered services listed in the plan of care. This iteration contains non-substantive changes which add language informing beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 by alerting the beneficiary to CMS' nondiscrimination practices and the availability of alternate forms of this notice if needed. There are no substantive changes. *Form Number:*

CMS-10280 (OMB control number: 0938-0829); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 12,459; *Total Annual Responses:* 13,764,434; *Total Annual Hours:* 917,262. (For policy questions regarding this collection contact Evelyn Blaemire at 410-786-1803).

Dated: October 20, 2015.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2015-27077 Filed 10-23-15; 8:45 am]

**BILLING CODE 4120-01P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2013-N-1282]

**National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions—Small Entity Compliance Guide; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions—Small Entity Compliance Guide." This guidance is intended to help small businesses understand the recent changes to FDA's National Environmental Policy Act (NEPA)-implementing regulations, which will allow certain classes of actions on tobacco product marketing applications to be excluded from the requirements to prepare an environmental assessment (EA) or an environmental impact statement (EIS). This will decrease the amount of time required for industry to complete, and for FDA to review, applications.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions)*: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions".

**Instructions:** All submissions received must include the Docket No. FDA-2013-N-1282 for "National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions—Small Entity Compliance Guide." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including

the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Katherine Collins, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, [CTPRegulations@fda.hhs.gov](mailto:CTPRegulations@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions—Small Entity Compliance Guide." This guidance is intended to help small

businesses understand and comply with FDA's implementation of NEPA and the Council on Environmental Quality (CEQ) regulations for classes of actions for tobacco products as provided by the final rule. Specifically, this guidance is intended to help small businesses understand which classes of actions for tobacco products require at least the preparation of an EA, and how to apply for categorical exclusions if they qualify based on their particular circumstance.

NEPA and CEQ regulations require each Federal Agency to assess, as an integral part of its decisionmaking process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment and to ensure that the interested and affected public is appropriately informed (42 U.S.C. 4332(2); 40 CFR 1506.6). FDA regulations governing its responsibilities under NEPA are codified at 21 CFR part 25, and the CEQ regulations are codified at 40 CFR parts 1500 to 1508.

CEQ oversees FDA's compliance with NEPA. For major Federal actions that may have a significant environmental impact, FDA can either prepare an EIS or prepare an EA. An EA provides sufficient information and analysis for FDA to determine whether to prepare an EIS or issue a finding of no significant impact (21 CFR 25.20; 40 CFR 1501.4). FDA is responsible for the scope and content of an EA and generally requires an applicant to prepare an EA and make necessary corrections to it (21 CFR 25.40(b)).

Categorically excluded actions refer to a category of actions that have been found not to individually or cumulatively have a significant effect on the quality of the human environment and which do not normally require the preparation of an EA or EIS (40 CFR 1508.4). However, as required under 21 CFR 25.21 and 40 CFR 1508.4, FDA will require preparation of at least an EA for any specific action that normally would be excluded if extraordinary circumstances are present such that the specific proposed action may have the potential to significantly affect the quality of the human environment. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121), FDA is making available this small entity compliance guide stating in plain language the legal requirements of the September 24, 2015, final rule, set forth in 21 CFR part 25.

##### II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on NEPA and environmental assessments for tobacco products including categorical exclusions. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

### III. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: October 20, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-27111 Filed 10-23-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Ancillary R01 Telephone Review SEP.

*Date:* November 10, 2015.

*Time:* 1:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-4719, [guox@extra.niddk.nih.gov](mailto:guox@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Treatments for Fecal Incontinence.

*Date:* December 2, 2015.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7637, [davila-bloom@extra.niddk.nih.gov](mailto:davila-bloom@extra.niddk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 20, 2015.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-27061 Filed 10-23-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Support of NIGMS Program Project Grants.

*Date:* November 16, 2015.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Margaret J. Weidman, Ph.D., Scientific Review Officer, Office of

Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, 301-594-3663, [weidmanma@nigms.nih.gov](mailto:weidmanma@nigms.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; NIGMS Support of Competitive Research (SCORE) Awards.

*Date:* November 17, 2015.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Margaret J. Weidman, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12N, Bethesda, MD 20892, 301-594-3663, [weidmanma@nigms.nih.gov](mailto:weidmanma@nigms.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Review of K99 and R01 Grant Applications.

*Date:* November 17, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard by Marriott Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

*Contact Person:* Lee Warren Slice, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12E, Bethesda, MD 20892, 301-435-0807, [slicelw@mail.nih.gov](mailto:slicelw@mail.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Support of Competitive Research (SCORE) Awards.

*Date:* November 18, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015

*Contact Person:* Nina Sidorova, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12K, Bethesda, MD 20892, 301-402-2783, [sidorova@nigms.nih.gov](mailto:sidorova@nigms.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 20, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-27059 Filed 10-23-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of an Interagency Autism Coordinating Committee (IACC or Committee) meeting.

The purpose of the IACC meeting is to introduce the members of the new committee and discuss business, agency updates and issues related to autism spectrum disorder (ASD) research and services activities. The meeting will be open to the public and will be accessible by webcast and conference call.

*Name of Committee:* Interagency Autism Coordinating Committee (IACC).

*Type of meeting:* Open Meeting.

*Date:* November 17, 2015.

*Time:* 9:30 a.m. to 5:00 p.m.\* Eastern Time \* Approximate end time.

*Agenda:* To introduce the members of the new committee and discuss business, updates and issues related to ASD research and services activities.

*Place:* Fishers Lane Conference Center, 5635 Fishers Lane, Room 508/509/510, Rockville, MD 20852.

*Webcast Live:* <http://videocast.nih.gov/>.

*Conference Call Access:* Dial: 1-888-946-7302, Access code: 1453351.

*Cost:* The meeting is free and open to the public.

*Registration:* Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis. To register, please visit: [www.iacc.hhs.gov](http://www.iacc.hhs.gov).

*Deadlines:* Notification of intent to present oral comments: Monday, November 9, 2015 by 5:00 p.m. ET. Submission of written/electronic statement for oral comments: Tuesday, November 10, 2015 by 5:00 p.m. ET. Submission of written comments: Tuesday, November 10, 2015 by 5:00 p.m. ET.

For IACC Public Comment guidelines, please see: <http://iacc.hhs.gov/public-comment/index.shtml>.

*Access:* Twinbrook Metro Station (Red Line).

*Contact Person:* Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6182A, Bethesda, MD 20892-9669, Phone: 301-443-6040, Email: [IACCPublicInquiries@mail.nih.gov](mailto:IACCPublicInquiries@mail.nih.gov).

### Public Comments

Any member of the public interested in presenting oral comments to the Committee must notify the Contact Person listed on this notice by 5:00 p.m. ET on Monday, November 9, 2015, with their request to present oral comments at the meeting. Interested individuals and representatives of organizations must submit a written/electronic copy of the oral presentation/statement including a brief description of the organization represented by 5:00 p.m. ET on Tuesday, November 10, 2015. Statements submitted will become a part of the public record. Only one representative of an organization will be allowed to present oral comments and presentations will be limited to three to five minutes per speaker, depending on the number of speakers to be accommodated within the allotted time. Speakers will be assigned a time to speak in the order of the date and time when their request to speak is received, along with the required submission of the written/electronic statement by the specified deadline.

In addition, any interested person may submit written public comments to the IACC prior to the meeting by sending the comments to the Contact Person listed on this notice by 5:00 p.m. ET on Tuesday, November 10, 2015. The comments should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. NIMH anticipates written public comments received by 5:00 p.m. ET, Tuesday, November 10, 2015 will be presented to the Committee prior to the meeting for the Committee's consideration. Any written comments received after the 5:00 p.m. EST, November 10, 2015 deadline through November 16, 2015 will be provided to the Committee either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. All written public comments and oral public comment statements received by the deadlines for both oral and written public comments will be provided to the IACC for their consideration and will become part of the public record.

In the 2009 IACC Strategic Plan, the IACC listed the "Spirit of Collaboration" as one of its core values, stating that, "We will treat others with respect, listen to diverse views with open minds, discuss submitted public comments, and foster discussions where participants can comfortably offer opposing opinions." In keeping with

this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also seek to treat others with respect and consideration in their communications and actions, even when discussing issues of genuine concern or disagreement.

### Remote Access

The meeting will be open to the public through a conference call phone number and Webcast live on the Internet. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the Webcast or conference call, please send an email to [helpdeskiacc@gmail.com](mailto:helpdeskiacc@gmail.com) or by phone at 415-652-8023.

Individuals who participate in person or by using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least 5 days prior to the meeting.

### Security

As part of security procedures, attendees should be prepared to present a photo ID at the meeting registration desk during the check-in process. Pre-registration is recommended. Seating will be limited to the room capacity and seats will be on a first come, first served basis, with expedited check-in for those who are pre-registered.

Meeting schedule subject to change.

Information about the IACC is available on the Web site: <http://www.iacc.hhs.gov>.

Dated: October 21, 2015.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-27122 Filed 10-23-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.



The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Skin Biology and Disease Resource Based Center.

*Date:* November 17–18, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Garden Inn Bethesda, 7301 Waverly St., Bethesda, MD 20814.

*Contact Person:* Kan Ma, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 814, Bethesda, MD 20892, 301–451–4838, [mak2@mail.nih.gov](mailto:mak2@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 21, 2015.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–27124 Filed 10–23–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Initial Review Group; Training and Workforce Development Subcommittee—A.

*Date:* November 18–19, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Washington DC/Rockville Hotel and Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* John J. Laffan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18J, Bethesda, MD 20892, 301–594–2773, [laffanjo@mail.nih.gov](mailto:laffanjo@mail.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Initial Review Group; Training and Workforce Development Subcommittee—C.

*Date:* November 19–20, 2015.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Ritz Carlton, Tysons Corner, 1700 Tysons Boulevard, McLean, VA 22102.

*Contact Person:* Mona R. Trempe, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12, Bethesda, MD 20892, 301–594–3998, [trempe@mail.nih.gov](mailto:trempe@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 20, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–27060 Filed 10–23–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

*Date:* October 29, 2015.

*Time:* 7:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Margaret Chandler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7814, Bethesda, MD 20892, (301) 435–1743, [margaret.chandler@nih.gov](mailto:margaret.chandler@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 20, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–27058 Filed 10–23–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Human Genome Research Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL HUMAN GENOME RESEARCH INSTITUTE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Human Genome Research Institute.

*Date:* October 28–29, 2015.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.



*Place:* National Institutes of Health, Building 31, Room 4B31, 31 Center Drive, Bethesda, MD 20892.

*Contact Person:* Monica Berger, Executive Secretary, Office of the Scientific Director, National Human Genome Research Institute, 50 South Drive, Bldg. 50, Rm 5222, Bethesda, MD 20892, 301-294-6873, [bergerm@mail.nih.gov](mailto:bergerm@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the intramural research review cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: October 21, 2015.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-27123 Filed 10-23-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2015-0895]

#### Information Collection Request to Office of Management and Budget; OMB Control Number: 1625-0033

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of revisions to the following collection of information: 1625-0033, Display of Fire Control Plans for Vessels. Our ICR describe the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before December 28, 2015.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG-2015-0895] to the Coast Guard using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the "Public participation and request for comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from:

COMMANDANT (CG-612), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR AVE SE., STOP 7710, WASHINGTON, DC 20593-7710.

**FOR FURTHER INFORMATION CONTACT:**

Contact Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek approval of revisions of the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG-2015-0895], and must be received by December 28, 2015.

**Submitting Comments**

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for

alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

**Information Collection Request**

1. *Title:* Display of Fire Control Plans for Vessels.1625-0033.

*Summary:* This information collection is for the posting or display of specific plans on certain categories of commercial vessels. The availability of these plans aid firefighters and damage control efforts in response to emergencies.

*Need:* Under 46 U.S.C. 3305 and 3306, the Coast Guard is responsible for ensuring the safety of inspected vessels and has promulgated regulations in 46 CFR parts 35, 78, 97, 109, 131, 169, and 196 to ensure that safety standards are met.

*Forms:* None.

*Respondents:* Owners and operators of vessels.

*Frequency:* On occasion.

*Hour Burden Estimate:* The estimated burden has decreased from 581 hours to 576 hours a year due to a decrease in the estimated number of respondents.

*Authority:* The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 18, 2015.

**Thomas P. Michelli,**

*U.S. Coast Guard, Deputy Chief Information Officer.*

[FR Doc. 2015-27021 Filed 10-23-15; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4241-DR; Docket ID FEMA-2015-0002]

#### South Carolina; Amendment No. 5 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of South Carolina (FEMA-4241-DR), dated October 5, 2015, and related determinations.

**DATES:** Effective Date: October 15, 2015.

**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:** The notice of a major disaster declaration for the State of South Carolina is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 5, 2015.

Abbeville, Anderson, Fairfield, Laurens, and McCormick Counties for Public Assistance.

Bamberg, Colleton, Darlington, Florence, Kershaw, and Newberry Counties for Public Assistance (already designated for Individual Assistance).

Berkeley, Georgetown, Richland, and Williamsburg Counties for Public Assistance (Categories C-G) (already designated for Individual Assistance and debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance 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. 2015-27188 Filed 10-23-15; 8:45 am]

**BILLING CODE 9111-23-P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4241-DR: Docket ID FEMA-2015-0002]

#### South Carolina; Amendment No. 4 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of South Carolina (FEMA-4241-DR), dated October 5, 2015, and related determinations.

**DATES:** *Effective Date:* October 13, 2015.

**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:** The notice of a major disaster declaration for the State of South Carolina is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 5, 2015.

Newberry County for Individual Assistance.

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. 2015-27189 Filed 10-23-15; 8:45 am]

**BILLING CODE 9111-23-P**

## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2015-0056]

### President's National Security Telecommunications Advisory Committee

**AGENCY:** National Protection and Programs Directorate, DHS.

**ACTION:** Committee Management; Notice of Partially Closed Federal Advisory Committee Meeting.

**SUMMARY:** The President's National Security Telecommunications Advisory Committee (NSTAC) will meet on Tuesday, November 10, 2015, in Washington, DC. The meeting will be partially closed to the public.

**DATES:** The NSTAC will meet in a closed session on Tuesday, November 10, 2015, from 8:30 a.m. to 10:45 a.m. and in an open session on Tuesday, November 10, 2015, from 11:00 a.m. to 2:20 p.m.

**ADDRESSES:** The open, public session will be held at the Department of Homeland Security Immigration and Customs Enforcement facility, 500 12th Street SW., Washington, DC, and will begin at 11:00 a.m. For information on facilities or services for individuals with disabilities, to request special assistance at the meeting, or to attend in person contact [nstac@dhs.gov](mailto:nstac@dhs.gov) as soon as possible and no later than Tuesday, November 3, 2015.

We are inviting public comment on the issues the NSTAC will consider, as listed in the **SUPPLEMENTARY INFORMATION** section below. Associated briefing materials that will be discussed at the meeting will be available at [www.dhs.gov/nstac](http://www.dhs.gov/nstac) for review as of October 27, 2015. Comments must be identified by docket number DHS-2015-0056 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Email:* [NSTAC@dhs.gov](mailto:NSTAC@dhs.gov). Include the docket number in the subject line of the message.

- *Fax:* 703-235-5962, Attn: Helen Jackson.

- *Mail:* Designated Federal Officer, National Security Telecommunications Advisory Committee, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane, Mail Stop 0604, Arlington, VA 20598-0604.

*Instructions:* All submissions received must include the words "Department of Homeland Security" and the docket number for this action. Comments

received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

**Docket:** For access to the docket to read background documents or comments received by the NSTAC, go to <http://www.regulations.gov>, referencing docket number DHS–DHS–2015–0056.

A public comment period will be held during the open portion of the meeting on Tuesday, November 10, 2015, from 1:55 p.m. to 2:10 p.m. and speakers are requested to limit their comments to three minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Please contact [Helen.Jackson@dhs.gov](mailto:Helen.Jackson@dhs.gov) to register as a speaker by close of business on November 8, 2015. Speakers will be accommodated in order of registration within the constraints of the time allotted to public comment.

**FOR FURTHER INFORMATION CONTACT:**

Helen Jackson, NSTAC Designated Federal Officer, Department of Homeland Security, telephone (703) 235–5321 or [Helen.Jackson@dhs.gov](mailto:Helen.Jackson@dhs.gov).

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the *Federal Advisory Committee Act*, 5 U.S.C. Appendix (Pub. L. 92–463). The NSTAC advises the President on matters related to national security and emergency preparedness (NS/EP) telecommunications policy.

**Agenda:** The committee will meet in the open session to receive an update on current engagement activities between the NSTAC and the NS/EP Communications Executive Committee. The NSTAC will also hold a panel discussion on high performance computing and big data convergence, focusing on public private and cross agency collaboration and the predictive analytics capabilities of big data. The NSTAC will receive brief remarks on the U.S. Department of Commerce's (DOC) progress in promoting Government's cybersecurity efforts since the adoption of the National Institute of Standards and Technology Cybersecurity Framework, the process and approach under which the DOC continues to seek partners for its cybersecurity initiatives, and how private sector participation helps to promote the DOC's cybersecurity efforts. In addition, the NSTAC will receive an update on the work of the NSTAC's examination of big data analytics. The meeting agenda will be available at [www.dhs.gov/nstac](http://www.dhs.gov/nstac) as of October 27, 2015.

The NSTAC will meet in a closed session to hear a classified briefing regarding current cyber threats against

the communications infrastructure, and to discuss potential future NSTAC study topics.

**Basis for Closure:** In accordance with 5 U.S.C. 552b(c), *The Government in the Sunshine Act*, it has been determined that two agenda items require closure as the disclosure of the information would not be in the public interest.

The first of these agenda items, the classified briefing, will provide members with information on current threats against the communications infrastructure. Disclosure of these threats would provide criminals who wish to intrude into commercial and Government networks with information on potential vulnerabilities and mitigation techniques, also weakening existing cybersecurity defense tactics. This briefing will be classified at the top secret level, thereby exempting disclosure of the content by statute. Therefore, this portion of the meeting is required to be closed pursuant to 5 U.S.C. 552b(c)(1)(A).

The second agenda item, the discussion of potential NSTAC study topics, will address areas of critical cybersecurity vulnerabilities and priorities for Government. Government officials will share data with NSTAC members on initiatives, assessments, and future security requirements across public and private networks. The data to be shared includes specific vulnerabilities within cyberspace that affect the Nation's communications and information technology infrastructures and proposed mitigation strategies. Disclosure of this information to the public would provide criminals with an incentive to focus on these vulnerabilities to increase attacks on our cyber and communications networks. Therefore, this portion of the meeting is likely to significantly frustrate implementation of proposed DHS actions and is required to be closed pursuant to 5 U.S.C. 552b(c)(9)(B).

Dated: October 20, 2015.

**Helen Jackson,**

*Designated Federal Officer for the NSTAC.*

[FR Doc. 2015–27101 Filed 10–23–15; 8:45 am]

**BILLING CODE 9110–9P–P**

## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2015–0017]

### Notice of Public Meeting Regarding Standards for Information Sharing and Analysis Organizations

**AGENCY:** Office of Cybersecurity and Communications, National Protection

and Programs Directorate, Department of Homeland Security.

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with EO 13691, DHS has entered into a cooperative agreement with a non-governmental ISAO Standards Organization led by the University of Texas at San Antonio with support from the Logistics Management Institute (LMI) and the Retail Cyber Intelligence Sharing Center (R–CISC). This Notice announces the ISAO Standards Organization's initial public meeting on November 9, 2015 to discuss Standards for the development of ISAOs, as related to Executive Order 13691, "Promoting Private Sector Cybersecurity Information Sharing" of February 13, 2015. This meeting builds off of the workshops held on June 9, 2015 at the Volpe Center in Cambridge, MA; and July 30, 2015 at San Jose State University in San Jose, CA.

**DATES:** The meeting will be held on November 9, 2015, from 8:00 a.m. to 5:00 p.m. The meeting may conclude before the allotted time if all matters for discussion have been addressed.

**ADDRESSES:** The meeting location is LMI Headquarters at 7940 Jones Branch Drive, Tysons, VA 22102. See *Supplementary Information section for the address to submit written or electronic comments.*

**SUPPLEMENTARY INFORMATION:** Executive Order 13691 can be found at: <https://www.whitehouse.gov/the-press-office/2015/02/13/executive-order-promoting-private-sector-cybersecurity-information-shari>.

**FOR FURTHER INFORMATION CONTACT:** If you have questions concerning the meeting, please contact [ISAO@lmi.org](mailto:ISAO@lmi.org).

### Background and Purpose

On February 13, 2015, President Obama signed Executive Order 13691 intended to enable and facilitate "private companies, nonprofit organizations, and executive departments and agencies . . . to share information related to cybersecurity risks and incidents and collaborate to respond in as close to real time as possible."

At the Standards Organization's initial public meeting, they intend to review the results of previous DHS-hosted public workshops, and share a proposed standards framework and standards development process. In addition, they will solicit suggestions on existing standards, guidelines, and best practices that can be shared as provisional guidance until formal ISAO standards are established. Minutes from

this meeting will be made available to the public.

### Information on Service for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact [ISAO@lmi.org](mailto:ISAO@lmi.org) and write "Special Assistance" in the subject box or contact the meeting coordinator at the **FOR FURTHER INFORMATION CONTACT** section of this notice.

### Meeting Details

Members of the public may attend this meeting by RSVP only up to the seating capacity of the room. The Breakout Panels that take place in the LMI Conference Facility will be audio recorded. The audio recordings will be made available on the DHS ISAO Web page, [DHS.gov/ISAO](http://DHS.gov/ISAO). A valid government-issued photo identification (for example, a driver's license) will be required for entrance to the meeting space. Those who plan to attend should RSVP through the link provided on the ISAO Web page [DHS.gov/ISAO](http://DHS.gov/ISAO) or at LMI's registration page [www.lmi.org/ISAO-Registration](http://www.lmi.org/ISAO-Registration) no later than 5 days prior to the meeting. Requests made after November 4, 2015 might not be able to be accommodated.

DHS and the ISAO Standards Organization encourages you to participate in this meeting by submitting comments to the ISAO inbox ([ISAO@lmi.org](mailto:ISAO@lmi.org)), commenting orally, or submitting written comments to the DHS personnel attending the meeting who are identified to receive them.

### Submitting Written Comments

You may also submit written comments to the docket using any one of the following methods:

(1) *Federal eRulemaking Portal*: <http://www.regulations.gov>. Although comments are being submitted to the Federal eRulemaking Portal, this is a tool to provide transparency to the general public, not because this is a rulemaking action.

(2) *Email*: [ISAO@lmi.org](mailto:ISAO@lmi.org). Include the docket number in the subject line of the message.

(3) *Mail*: ISAO Standards Organization, c/o LMI, 1777 NE Loop 410, Suite 808, San Antonio, TX 78217-5217.

To avoid duplication, please use only one of these three methods. All comments must either be submitted to the online docket on or before November 4, 2015, or reach the Docket Management Facility by that date.

**Authority**: 6 U.S.C. 131–134; 6 CFR 29; E.O.13691.

Dated: October 20, 2015.

**Andy Ozment**,

*Assistant Secretary, Cybersecurity and Communications, National Protection and Programs Directorate, Department of Homeland Security.*

[FR Doc. 2015–27102 Filed 10–23–15; 8:45 am]

**BILLING CODE 9110–9P–P**

## DEPARTMENT OF HOMELAND SECURITY

### Transportation Security Administration

#### Intent To Request Renewal From OMB of One Current Public Collection of Information: Office of Law Enforcement/Federal Air Marshal Service Mental Health Certification

**AGENCY**: Transportation Security Administration, DHS.

**ACTION**: 60-day notice.

**SUMMARY**: The Transportation Security Administration (TSA) invites public comment on one currently approved Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0043, abstracted below, that we will submit to OMB for renewal in compliance with the Paperwork Reduction Act. The ICR describes the nature of the information collection and its expected burden. The collection involves a certification form that applicants for the Office of Law Enforcement/Federal Air Marshal Service are required to complete regarding their mental health history.

**DATES**: Send your comments by December 28, 2015.

**ADDRESSES**: Comments may be emailed to [TSAPRA@dhs.gov](mailto:TSAPRA@dhs.gov) or delivered to the TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011.

**FOR FURTHER INFORMATION CONTACT**: Christina A. Walsh at the above address, or by telephone (571) 227–2062.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at <http://www.reginfo.gov>. Therefore, in preparation for OMB review and approval of the following

information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

#### Information Collection Requirement

Pursuant to 49 U.S.C. 44917, TSA has authority to provide for deployment of Federal Air Marshals (FAMs) on passenger flights and provide for appropriate training, equipping, and supervision of FAMs. In furtherance of this authority, TSA policy requires that applicants for the Office of Law Enforcement/Federal Air Marshal Service positions meet certain medical and mental health standards.

In order to evaluate whether applicants meet TSA standards, applicants must undergo a psychological evaluation determining that they do not have an established medical history or clinical diagnosis of psychosis, neurosis, or any other personality or mental disorder that clearly demonstrates a potential hazard to the performance of FAM duties or the safety of self or others. As part of the psychological evaluation, applicants are required to complete a certification form regarding their mental health history and provide an explanation for anything they cannot certify. Applicants will be asked whether they can certify various statements including that they have never been removed from work for medical or psychological reasons.

Upon completion, applicants submit the certification form directly to the FAMS' Medical Programs Section (FAMS MPS) for initial screening via fax, electronic upload via scanning document, mail, or in person. The FAMS MPS screens all certification forms received. Any explanations for uncertified items received will generally require further review and follow-up by a personal psychologist or psychiatrist. This certification is carefully geared to capitalize on other elements of the assessment process, such as personal interviews, physical task assessment, background investigation, as well as the other components of the medical

examination and assessment. TSA estimates that there will be 600 respondents annually.

It will take each respondent approximately one hour to complete the certification form for a total annual hour burden of 600 hours.

Dated: October 19, 2015.

**Christina A. Walsh,**

*TSA Paperwork Reduction Act Officer, Office of Information Technology.*

[FR Doc. 2015-27094 Filed 10-23-15; 8:45 am]

BILLING CODE 9910-05-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-R1-ES-2015-N191;  
FXES11120100000-156-FF01E00000]

#### **Draft Habitat Conservation Plan and Draft Environmental Assessment, Meier Group LLC, Thurston County, Washington**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), have received an application from The Meier Group, LLC (applicant) for an incidental take permit (permit) under the Endangered Species Act of 1973, as amended (ESA). The applicant requests a permit with a 5-year term that would authorize “take” of the threatened Olympia pocket gopher incidental to otherwise lawful land development in Thurston County, Washington. The application includes the applicant’s draft habitat conservation plan (HCP), which describes the actions the applicant will implement to minimize and mitigate the impacts of incidental take caused by covered activities. The Service also announces the availability of a draft environmental assessment (EA) that has been prepared in response to the permit application in accordance with requirements of the National Environmental Policy Act (NEPA). We are making the permit application, including the draft HCP and the draft EA, available for public review and comment.

**DATES:** To ensure consideration, please submit written comments by December 28, 2015.

**ADDRESSES:** To request further information or submit written comments, please use one of the following methods, and note that your information request or comments are in reference to the “Meier HCP/EA”:

- **Internet:** You may view or download copies of the draft HCP and draft EA and obtain additional information on the Internet at <http://www.fws.gov/wafwo/>.

- **Email:** [www.wfwocomments@fws.gov](mailto:www.wfwocomments@fws.gov). Include “Meier HCP/EA” in the subject line of the message.

- **U.S. Mail:** Tim Romanski, U.S. Fish and Wildlife Service, Washington Fish and Wildlife Office, 510 Desmond Drive SE., Suite 102, Lacey, Washington 98503.

- **In-Person Drop-off, Viewing, or Pickup:** Call 360-753-5823 to make an appointment (necessary for viewing or picking up documents only) during normal business hours at the U.S. Fish and Wildlife Service, Washington Fish and Wildlife Office, 510 Desmond Drive SE., Suite 102, Lacey, Washington 98503. Written comments can be dropped off during regular business hours at the above address on or before the closing date of the public comment period (see **DATES**).

**FOR FURTHER INFORMATION CONTACT:** Tim Romanski, Conservation Planning and Hydropower Branch Chief, Washington Fish and Wildlife Office (see **ADDRESSES**), telephone: 360-753-5823. If you use a telecommunications device for the deaf, please call the Federal Information Relay Service at 800-877-8339.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

Section 9 of the ESA prohibits “take” of fish and wildlife species listed as endangered or threatened. Under the ESA, the term “take” means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct (16 U.S.C. 1532(19)). The term “harm,” as defined in our regulations, includes significant habitat modification or degradation that results in death or injury to listed species by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering (50 CFR 17.3). The term “harass” is defined in our regulations as an intentional or negligent act or omission which creates the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavioral patterns, which include, but are not limited to, breeding, feeding, or sheltering (50 CFR 17.3).

Under specified circumstances, the Service may issue permits that authorize take of federally listed species, provided the take is incidental to, but not the purpose of, an otherwise lawful activity. Regulations governing permits for

endangered and threatened species are at 50 CFR 17.22 and 17.32, respectively. Section 10(a)(1)(B) of the Act contains provisions that authorize the Service to issue permits to non-Federal entities for the take of endangered and threatened species, provided the following criteria are met:

- (1) The taking will be incidental;
- (2) The applicant will prepare a conservation plan that, to the maximum extent practicable, minimize and mitigate the impact of such taking;
- (3) The applicant will ensure that adequate funding for the plan will be provided;
- (4) The taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild; and

- (5) The applicant will carry out any other measures that the Service may require as being necessary or appropriate for the purposes of the plan.

We have received an application from the Meier Group, LLC (applicant) for an incidental take permit pursuant to Section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (ESA). The applicant requests a permit with a 5-year term that would authorize “take” of the threatened Olympia pocket gopher (*Thomomys mazama pugetensis*) incidental to otherwise lawful land development and habitat conservation activities on land they own in Thurston County, Washington. The application includes a draft HCP, which describes the actions the applicant will take to minimize and mitigate the impacts of the take on the covered species. The Service also announces the availability of a draft environmental assessment (EA) addressing the draft HCP and proposed permit. We invite comments from all interested parties regarding the permit application, including the draft HCP and the draft EA.

##### **Proposed Action**

The applicant proposes to develop an approximately 6.4-acre property in the City of Tumwater, Thurston County, Washington, over the course of the next 5 years. The proposed project would entail clearing most of the 6.4-acre property of trees and other vegetation, including the invasive non-native Scot’s broom (*Cytisus scoparius*), in preparation for construction of a two-story commercial office building and associated facilities. The proposed office building, paved surfaces, and parking areas would cover all of the property except an approximately 0.7-acre area that would be avoided to prevent impacts to guy-wires associated with overhead electric transmission lines.

Approximately 2.7 acres of the 6.4-acre property is occupied by and provides habitat for the Olympia pocket gopher. Periodic mowing of the transmission line right-of-way keeps invasive vegetation controlled, which likely maintains habitat suitability for the pocket gopher. About 2.0 acres of the approximately 2.7 acres of potential pocket gopher habitat on the project site would be lost due to site preparation and construction activities under the proposed project. Olympia pocket gophers and their habitat would not be expected to persist in this area upon completion of the proposed project. Approximately 0.7 acre of the degraded grassland area beneath the transmission lines would remain undisturbed. Any pocket gophers in the remnant habitat patch may be able to survive for some period of time after project completion; however, the fragmentation, loss of foraging habitat, and reproductive isolation of remaining individuals makes long-term persistence of a viable population in this area unlikely.

The applicant's draft HCP identifies measures intended to minimize and mitigate for the incidental take of the covered species. The draft HCP's mitigation measures consist of a conservation program that includes dedication of an off-site 2.5-acre permanent conservation land area at a location known as Bush Prairie Farm, that would be managed for the benefit of the Olympia pocket gopher. The proposed HCP would establish a conservation easement on Bush Prairie Farm that removes the threat of future development on the conservation site, and provide funding to ensure that the conservation site is managed to maintain long-term habitat suitability for the covered species. The Bush Prairie Farm 2.5-acre conservation site is approximately 1,000 feet away from the only designated critical habitat for the Olympia pocket gopher. The conservation site is separated by a highway from the 676 acres of designated critical habitat that is located on the Olympia Regional Airport property. The conservation site is also adjacent to other sites proposed for long-term management for the listed species. Securing long-term protection and management of the proposed conservation site could expand priority conservation areas that may contribute to recovery of this species.

The Service proposes to issue the requested permit with a 5-year term based on the applicant's commitment to implement the draft HCP, if permit issuance criteria are met. Covered activities include construction, land development, and conservation of

covered species. The area covered under the draft HCP consists of a project development site totaling 6.4 acres and a conservation site totaling 2.5 acres. Take would occur primarily on the already fragmented project development site and be mitigated for by managing a higher quality block of habitat for the covered species on the conservation site. A conservation easement with associated funding assurances would be executed by the applicant to ensure ongoing management of the conservation site.

#### **National Environmental Policy Act Compliance**

The proposed issuance of a permit is a Federal action that triggers the need for compliance with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*; NEPA). Pursuant to NEPA, we have prepared a draft EA to analyze the environmental impacts of three alternatives related to the issuance of the requested permit and implementation of the conservation program under the proposed HCP. The three alternatives analyzed in the EA are a no-action alternative, the proposed action, and an avoidance alternative.

*No-action alternative:* Under the no-action alternative, no construction or development would occur on the proposed project site. Because no impacts to listed species are expected under this alternative, no HCP would be needed and no permit would be issued.

*Proposed action alternative:* The proposed action alternative is the implementation of the proposed HCP and issuance of the requested 5-year permit as described above.

*Avoidance alternative:* The avoidance alternative would limit construction and development on the project site to areas where impacts to listed species could be avoided. Because no impacts to listed species are expected under this alternative, no HCP would be needed and no permit would be issued.

#### **Public Comments**

You may submit your comments and materials by one of the methods listed in the **ADDRESSES** section. We specifically request information, views, and recommendations from interested parties regarding our proposed Federal action, including identification of any other aspects of the human environment not already identified in the draft EA pursuant to NEPA regulations at 40 CFR 1506.6. Further, we specifically solicit information regarding the adequacy of the applicant's draft HCP pursuant to the requirements for permits at 50 CFR parts 13 and 17.

#### **Public Availability of Comments**

All comments and materials we receive become part of the public record associated with this action. Before including your address, phone number, email address, or other personally identifiable information in your comments, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety. Comments and materials we receive, as well as supporting documentation we use in preparing the EA, will be available for public inspection by appointment, during normal business hours, at our Washington Fish and Wildlife Office (see **ADDRESSES**).

#### **Next Steps**

We will evaluate the permit application, associated documents, and any comments we receive, to determine whether the permit application meets the requirements of section 10(a)(1)(B) of the ESA. We will also evaluate whether issuance of the requested section 10(a)(1)(B) permit would comply with section 7 of the Act by conducting an intra-Service section 7 consultation on anticipated permit actions. After completion of the EA based on consideration of public comments, we will determine whether the proposed action warrants a finding of no significant impact or whether an environmental impact statement should be prepared. The final NEPA and permit determinations will not be completed until after the end of the 30-day comment period and will fully consider all comments received during the comment period. If we determine that all requirements are met, we will issue an incidental take permit under section 10(a)(1)(B) of the ESA to the applicants for the take of covered species, incidental to otherwise lawful covered activities.

#### **Authority**

We provide this notice in accordance with the requirements of section 10 of the Act (16 U.S.C. 1531 *et seq.*) and NEPA (42 U.S.C. 4321 *et seq.*) and their

implementing regulations (50 CFR 17.22 and 40 CFR 1506.6, respectively).

**Richard Hannan,**

*Deputy Regional Director, Pacific Region, U.S. Fish and Wildlife Service, Portland, Oregon.*

[FR Doc. 2015–27149 Filed 10–23–15; 8:45 am]

BILLING CODE 4333–15–P

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

[FWS–HQ–WSFR–2015–

N195;FVWF97820900000–XXX–FF09W13000 and FVWF54200900000–XXX–FF09W13000]

**Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; National Survey of Fishing, Hunting, and Wildlife-Associated Recreation (FHWAR)**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice; request for comments.

**SUMMARY:** We (U.S. Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

**DATES:** You must submit comments on or before November 25, 2015.

**ADDRESSES:** Send your comments and suggestions on this information collection 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 Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail), or *hope\_grey@fws.gov* (email). Please include “1018–0088” in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR, contact Hope Grey at *hope\_grey@fws.gov* (email) or 703–358–2482 (telephone). You may view the ICR online at <http://www.reginfo.gov>. Follow the instructions to view Department of the Interior collections under review by OMB.

**SUPPLEMENTARY INFORMATION:**

**Information Collection Request**

*OMB Control Number:* 1018–0088.

*Title:* National Survey of Fishing, Hunting, and Wildlife-Associated Recreation (FHWAR).

*Service Form Number:* None.

*Type of Request:* Reinstatement with change of a previously approved collection.

*Description of Respondents:* Individuals and households.

*Respondent's Obligation:* Voluntary.

*Frequency of Collection:* Pre-screener internet/paper questionnaire data collection will be conducted in January 2016. Household screen interviews and the first detailed sportsperson and wildlife-watcher interviews will be conducted April–June 2016. The second detailed interviews will be conducted September–October 2016. The third and last detailed interviews will be conducted January–March 2017.

*Estimated Number of Annual Responses:* 29,179.

*Estimated Completion Time per Response:* Varies from 5 to 35 minutes.

*Estimated Total Annual Burden Hours:* 6,355.

*Estimated Annual Non-hour Burden Cost:* None.

*Abstract:* The information collected for the National Survey of Fishing, Hunting and Wildlife-Associated Recreation (FHWAR) assists the Fish and Wildlife Service in administering the Wildlife and Sport Fish Restoration grant programs. The 2016 FHWAR will provide up-to-date information on the uses and demands for wildlife-related recreation resources, trends in uses of those resources, and a basis for developing and evaluating programs and projects to meet existing and future needs.

We collect the information in conjunction with carrying out our responsibilities under the Federal Aid in Sport Fish Restoration Act (16 U.S.C. 777–777m), commonly referred to as the Dingell-Johnson Act, and the Federal Aid in Wildlife Restoration Act (16 U.S.C. 669–669i), commonly referred to as the Pittman-Robertson Act. Under these acts, as amended, we provide approximately \$1 billion in grants annually to States for projects that support sport fish and wildlife management and restoration, including:

- Improvement of fish and wildlife habitats,
- Fishing and boating access,
- Fish stocking, and
- Hunting and fishing opportunities.

We also provide grants for aquatic education and hunter education, maintenance of completed projects, and research into problems affecting fish and wildlife resources. These projects help to ensure that the American people have adequate opportunities for fish and wildlife recreation.

We conduct the survey about every 5 years. The 2016 FHWAR will be the 12th conducted since 1955. We sponsor the survey at the States' request, which is made through the Association of Fish and Wildlife Agencies. We contract with the Census Bureau, which collects the information using computer-assisted telephone or in-person interviews. The Census Bureau will select a sample of sportspersons and wildlife watchers from a household screen and conduct three detailed interviews during the survey year. The survey collects information on the number of days of participation, species of animals sought, and expenditures for trips and equipment. Information on the characteristics of participants includes age, income, sex, education, race, and State of residence.

Federal and State agencies use information from the survey to make policy decisions related to fish and wildlife restoration and management. Participation patterns and trend information help identify present and future needs and demands. Land managing agencies use the data on expenditures and participation to assess the value of wildlife-related recreational uses of natural resources. Wildlife-related recreation expenditure information is used to estimate the economic impact on the economy and to support the dedication of tax revenues for fish and wildlife restoration programs.

**Comments Received and Our Responses**

*Comments:* On February 18, 2015, we published in the **Federal Register** (80 FR 8681) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on April 20, 2015. We received two comments, both from the same individual. This individual was concerned that the survey estimates are presented as aggregations of wildlife watching, hunting, and fishing data, suggesting this biases the results toward hunting and fishing and away from wildlife watching. The Census Bureau draws scientifically designed separate samples of wildlife watchers and sportspersons. These samples are interviewed independently, and estimates of each activity are tabulated separately in the Survey reports. We did not make any changes to the survey based on these comments.

**Request for Public Comments**

We again 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 estimate of the burden for this collection of information;
- 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.

Comments that you submit in response to this notice are a matter of public record. 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 OMB and us in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: October 21, 2015.

**Tina A. Campbell,**

*Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.*

[FR Doc. 2015-27141 Filed 10-23-15; 8:45 am]

**BILLING CODE 4333-15-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

[167A2100DD/AAKC001030/  
A0A501010.999900]

### Renewal of Agency Information Collection for the Tribal Reassumption of Jurisdiction Over Child Custody Proceedings

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of submission to OMB.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the Bureau of Indian Affairs (BIA) is seeking comments on the renewal of Office of Management and Budget (OMB) approval for the collection of information for the Tribal Reassumption of Jurisdiction over Child Custody Proceedings, authorized by OMB Control Number 1076-0112. This information collection expires November 30, 2015.

**DATES:** Submit comments on or before November 25, 2015.

**ADDRESSES:** You may submit comments on the information collection to the Desk Officer for the Department of the Interior at the Office of Management and

Budget, by fax to (202) 395-5806 or you may send an email to: *OIRA Submission@omb.eop.gov*. Please send a copy of your comments to: Evangeline Campbell, Chief, Division of Human Services, Office of Indian Services, Bureau of Indian Affairs, 1849 C Street NW., MS-4513-MIB, Washington, DC 20240; facsimile: (202) 208-5113; email: *vangelina.Campbell@bia.gov*.

#### FOR FURTHER INFORMATION CONTACT:

Evangeline Campbell, (202) 513-7621. You may review the information collection request online at *http://www.reginfo.gov*. Follow the instructions to review Department of the Interior collections under review by OMB.

#### SUPPLEMENTARY INFORMATION:

##### I. Abstract

The BIA is seeking to renew the information collection conducted under 25 CFR 13, Tribal Reassumption of Jurisdiction over Child Custody Proceedings, which prescribes procedures by which an Indian tribe that occupies a reservation over which a State asserts any jurisdiction pursuant to Federal law may reassume jurisdiction over Indian child proceedings as authorized by the Indian Child Welfare Act, Public Law 95-608, 92 Stat. 3069, 25 U.S.C. 1918.

##### II. Request for Comments

On August 17, 2015, BIA published a notice announcing the renewal of this information collection and provided a 60-day comment period in the **Federal Register** (80 FR 49264). There were no comments received in response to this notice.

The BIA requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) Ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) Ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it has a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. Before including your address, phone

number, email address or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

#### III. Data

*OMB Control Number:* 1076-0112.

*Title:* Tribal Reassumption of Jurisdiction over Child Custody Proceedings, 25 CFR 13.

*Brief Description of Collection:* The collection of information will ensure that the provisions of Public Law 95-608 are met. Any Indian tribe that became subject to State jurisdiction pursuant to the provisions of the Act of August 15, 1953 (67 Stat. 588), as amended by title IV of the Act of April 11, 1968 (82 Stat. 73, 78), or pursuant to any other Federal law, may reassume jurisdiction over child custody proceedings. The collection of information provides data that will be used in considering the petition and feasibility of the plan of the tribe for reassumption of jurisdiction over Indian child custody proceedings. We collect the following information: Full name, address, and telephone number of petitioning tribe or tribes; a tribal resolution; estimated total number of members in the petitioning tribe of tribes with an explanation of how the number was estimated; current criteria for tribal membership; citation to provision in tribal constitution authorizing the tribal governing body to exercise jurisdiction over Indian child custody matters; description of tribal court; copy of any tribal ordinances or tribal court rules establishing procedures or rules for exercise of jurisdiction over child custody matters; and all other information required by 25 CFR 13.11. Response is required to obtain or retain a benefit.

*Type of Review:* Extension without change of currently approved collection.

*Respondents:* Federally recognized Indian tribes who submit tribal reassumption petitions for review and approval by the Secretary of the Interior.

*Annual Number of Responses:* 1.

*Obligation to Respond:* Response required to obtain a benefit.

*Estimated Time per Response:* 8 hours.

*Estimated Total Annual Hour Burden:* 8 hours.



*Estimated Total Annual Non-Hour Dollar Cost: \$0.*

**Elizabeth K. Appel,**

*Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.*

[FR Doc. 2015–27135 Filed 10–23–15; 8:45 am]

**BILLING CODE 4337–15–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**16X.LLAZ956000.L1440000.BJ0000.  
LXSSA225000.241A**

#### Notice of Filing of Plats of Survey; Arizona

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Filing of Plats of Survey; Arizona.

**SUMMARY:** The plats of survey of the described lands were officially filed in the Arizona State Office, Bureau of Land Management, Phoenix, Arizona, on dates indicated.

#### SUPPLEMENTARY INFORMATION:

##### The Gila and Salt River Meridian, Arizona

The plat representing the dependent resurvey and subdivision of section 4, Township 22 North, Range 6 East, accepted September 28, 2015, and officially filed September 30, 2015, for Group 1123, Arizona.

This plat was prepared at the request of the United States Forest Service.

The plat, in seven sheets, representing the dependent resurvey, subdivision of certain sections, metes-and-bounds surveys in section 27 and 35, and recovery of certain corners, Township 23 North, Range 6 East, accepted September 28, 2015, and officially filed September 30, 2015, for Group 1123, Arizona.

This plat was prepared at the request of the United States Forest Service.

The plat representing the dependent resurvey and subdivision of section 18, Township 23 North, Range 7 East, accepted September 28, 2015, and officially filed September 30, 2015, for Group 1123, Arizona.

This plat was prepared at the request of the United States Forest Service.

The plat representing the dependent resurvey, corrective resurvey, independent resurvey and subdivision of certain sections, Township 21 North, Range 30 East, accepted September 29, 2015, and officially filed September 30, 2015, for Group 957, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat representing the dependent resurvey of a portion of the exterior boundary of the Gila River Indian Reservation in section 5, Township 5 South, Range 8 East, accepted April 7, 2015, and officially filed April 8, 2015, for Group 1135, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

A person or party who wishes to protest against any of these surveys must file a written protest with the Arizona State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within thirty (30) days after the protest is filed.

#### FOR FURTHER INFORMATION CONTACT:

These plats will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona 85004–4427. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**Gerald T. Davis,**

*Chief Cadastral Surveyor of Arizona.*

[FR Doc. 2015–27125 Filed 10–23–15; 8:45 am]

**BILLING CODE 4310–32–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[LLWYP07000.LL13100000.DB0000]**

#### Notice of Intent To Prepare an Environmental Impact Statement for the Greater Crossbow Oil and Gas Project and Possible Amendments to the Casper Resource Management Plan, Wyoming

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of intent.

**SUMMARY:** In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), the Federal Land Policy and Management Act of 1976, as amended (FLPMA), and the Mineral Leasing Act of 1920, as amended, the Bureau of Land Management (BLM), as lead agency, through the Buffalo Field Office, Buffalo, Wyoming, intends to prepare an

Environmental Impact Statement (EIS) for EOG Resources Inc.'s (EOG's) proposed Greater Crossbow Oil and Gas Project (Project). The proposal area includes Federal lands administered by the BLM's Buffalo and Casper Field Offices and the U.S. Forest Service's (USFS) Thunder Basin National Grasslands. This notice initiates the public scoping process for the EIS and potential land use plan amendments. The purpose of the public scoping process is to seek input and identify issues regarding the Project.

**DATES:** Comments may be submitted in writing until December 10, 2015. In order to be considered in the Draft EIS, all comments must be received prior to the close of the 45-day scoping period or 15 days after the last public meeting, whichever is later. The BLM will provide additional opportunities for public participation as appropriate. The dates and locations of any scoping meetings will be announced at least 15 days in advance through the local news media, newspapers, and the BLM Web site at: [http://www.blm.gov/wy/st/en/field\\_offices/Bufalo.html](http://www.blm.gov/wy/st/en/field_offices/Bufalo.html).

**ADDRESSES:** You may submit written comments by any of the following methods:

- *Web site:* <http://www.blm.gov/wy/st/en/info/NEPA/documents/bfo/GC.html>.
- *Email:*  
[BLM\\_WY\\_BuffaloGCEIS@blm.gov](mailto:BLM_WY_BuffaloGCEIS@blm.gov).
- *Fax:* 307–684–1122.
- *Mail:* Greater Crossbow Oil and Gas Project, BLM Buffalo Field Office, 1425 Fort Street, Buffalo, Wyoming 82834.

Documents pertinent to this proposal are available for public review at the BLM Buffalo Field Office or the USFS Douglas Ranger District Office, 2250 E. Richards Street, Douglas, Wyoming.

#### FOR FURTHER INFORMATION CONTACT:

Thomas Bills, NEPA Coordinator, telephone: 307–684–1133; address: 1425 Fort Street, Buffalo, Wyoming 82834; email:

[BLM\\_WY\\_BuffaloGCEIS@blm.gov](mailto:BLM_WY_BuffaloGCEIS@blm.gov). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact Mr. Bills 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. You may call either of these numbers to have your name added to our mailing list.

#### SUPPLEMENTARY INFORMATION:

EOG proposes to develop 1,500 oil and natural gas wells on 100 multi-well

pads over a 10-year period. As part of this development, EOG proposes to:

- Use directional, vertical, horizontal, and other drilling techniques;
- Develop area infrastructure to support oil and gas production, including well pads, roads, pipelines, power lines, compressor and electrical substations, and support facilities, such as water supply wells and water disposal facilities;
- Conduct year-round drilling where seasonal raptor restrictions may otherwise apply.

Surface disturbance associated with the proposal is estimated to include 7,000 acres of initial surface disturbance for the construction of new roads, well pads, pipelines, and support facilities, of which approximately 3,700 acres of surface disturbance may remain for the life of the project.

The proposal area lies between the towns of Wright and Bill, primarily west of Wyoming Highway 59, and includes approximately 120,000 acres. The USFS manages about 5,700 surface acres, or 5 percent of the Project area surface. The remainder of surface area affected by the proposal is privately owned (88 percent) or held by the State of Wyoming (7 percent). The BLM does not manage any of the surface area potentially affected by the Project. The proposal area includes about 74,000 acres (62 percent of the area) of BLM-administered Federal mineral estate. The remainder of the mineral estate in the Project area is privately owned (30 percent) or held by the State of Wyoming (8 percent). The BLM has identified the following preliminary issues: Greater sage-grouse and raptor conservation, especially ferruginous hawks; year-round drilling where seasonal raptor restrictions may otherwise apply; potential conflicts with coal mining and other area resource uses; air quality; ground and surface waters and water injection sites affected by the proposal; area transportation; the level of anticipated development of oil and gas resources in the planning area; and, the identification of opportunities to apply mitigation hierarchy strategies for on-site, regional, and compensatory mitigation, and, as appropriate, landscape-level conservation and management actions to achieve resource objectives.

Authorization of this proposal may require amendment of the Casper Field Office, Casper Resource Management Plan (RMP). Similarly, the USFS, as cooperating agency, may use the EIS analysis to support preparation of a land use plan amendment for the Thunder Basin National Grassland, Land and Resource Management Plan (LRMP), if appropriate. By this notice, the BLM is

complying with the requirements in 43 CFR 1610.2(c) to notify the public of potential amendments to land use plans, based on the findings of the EIS for the Project. If land use plan amendments are necessary or appropriate, the BLM will integrate the land-use planning processes with the NEPA process for this project.

The BLM is announcing the beginning of a scoping process to solicit public comments and identify issues associated with the Public. The BLM seeks resource information and data for public land values (e.g., air quality, cultural and historic resources, fire/fuels, fisheries, forestry, lands and realty, non-energy minerals and geology, oil and gas including coalbed natural gas, paleontology, rangeland management, recreation, soil, water, and wildlife) in the Project area. The purpose of this process is to ensure that the BLM's analysis of the Project has sufficient information and data to consider a reasonable range of resource uses, management options, and alternatives for managing public lands. The EIS for the Project will incorporate elements of the Wyoming Core Population Strategy and the BLM's Greater Sage-Grouse planning effort and decisions (76 FR 77008, December 9, 2011).

In connection with its evaluation of any authorizations and actions proposed in the EIS, the BLM will determine if those actions conform to the decisions in the current and proposed land use plans for the Project area. Any proposed actions that would change the scope of resource uses, terms and conditions, and decisions of these plans may require amendment of the affected plan(s). If the BLM determines that a plan amendment is necessary, it would conduct the appropriate analysis simultaneously with preparation of the EIS for the Project. The planning criteria for any necessary plan amendment will follow that found in the affected plan(s).

To provide the public with an opportunity to review the proposal and associated information, as well as any proposed plan amendments, the BLM will host public meetings on or before November 25, 2015. The BLM will notify the public of the precise date of such meetings and any other opportunities for the public to be involved in the process at least 15 days prior to the event via news release to the media, individual mailings, and postings on the BLM's Project Web site.

The BLM will use and coordinate the NEPA commenting process to help fulfill the public involvement process under section 106 of the National Historic Preservation Act (NHPA) (16 U.S.C. 470f), as provided for in 36 CFR

800.2(d)(3). Information about historic and cultural resources in the area potentially affected by the Project will assist the BLM in identifying and evaluating impacts to such resources in the context of both NEPA and section 106 of the NHPA. Native American tribal consultations will be conducted in accordance with applicable policy, and tribal concerns will be given due consideration. Federal, State, and local agencies, along with other stakeholders that may be interested or affected by the BLM's decisions on this proposal, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate as a cooperating agency.

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 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.

**Authority:** 40 CFR 1501.7, 43 CFR 1610.2.

**Mary Jo Rugwell,**

*Acting State Director.*

[FR Doc. 2015-27191 Filed 10-23-15; 8:45 am]

**BILLING CODE 4310-22-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[LLES962000 L14200000.B0000 15X]

#### Eastern States: Filing of Plats of Survey

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of filing of plats of survey; Minnesota.

**SUMMARY:** The Bureau of Land Management (BLM) will file the plats of survey of the lands described below in the BLM-Eastern States Office, Washington, DC, 30 calendar days from the date of publication in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Bureau of Land Management, Eastern States Office, 20 M Street SE., Washington DC, 20003. Attn: Cadastral Survey. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week,

to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** Survey in the Fifth Principal Meridian requested by the Bureau of Indian Affairs. Surveys in the Fourth Principal Meridian were requested by the U.S. Forest Service.

The lands surveyed are:

**Fourth Principal Meridian, Minnesota**

T. 64 N., R. 11 W.

The plat of survey represents the dependent resurvey of the south boundary of Township 64 North, Range 11 West, of the Fourth Principal Meridian, in the State of Minnesota, and was accepted September 28, 2015.

**Fourth Principal Meridian, Minnesota**

T. 64 N., R. 10 and 11 W.

The plat of survey represents the dependent resurvey of a portion of the range line between Townships 63 North, Ranges 10 and 11 West, and a portion of the south exterior boundary of Township 64 North, Range 10 West, of the Fourth Principal Meridian, in the State of Minnesota, and was accepted September 28, 2015.

**Fifth Principal Meridian, Minnesota**

T. 144 N., R. 39 W. and T. 143 N., R. 39 W.

The plat of survey represents the corrective dependent resurvey of a portion of the subdivisional lines and the corrective survey of the subdivision of sections 22–27, and 36, Township 144 North, Range 39 West, and the corrective dependent resurvey of a portion of the east boundary and the corrective survey of the subdivision of section 1, Township 143 North, Range 39 West, of the Fifth Principal Meridian, in the State of Minnesota, and was accepted September 28, 2015.

We will place a copy of the plat we described in the open files. It will be available to the public as a matter of information.

If BLM receives a protest against this survey, as shown on the plat, prior to the date of the official filing, we will stay the filing pending our consideration of the protest.

We will not officially file the plat until the day after we have accepted or dismissed all protests and they have become final, including decisions on appeals.

Dated: October 7, 2015.

**Dominica VanKoten,**

*Chief Cadastral Surveyor.*

[FR Doc. 2015–27126 Filed 10–23–15; 8:45 am]

**BILLING CODE 4310–GJ–P**

**INTERNATIONAL TRADE COMMISSION**

[Investigation No. 337–TA–938]

**Certain Coaxial Cable Connectors and Components Thereof and Products Containing Same Commission Determination Not To Review an Initial Determination Terminating the Investigation in Its Entirety Based Upon Withdrawal of the Complaint**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (“ID”) (Order No. 10) of the presiding administrative law judge (“ALJ”) granting complainant’s motion to withdraw the complaint and terminate the investigation in its entirety.

**FOR FURTHER INFORMATION CONTACT:** Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–3042. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at <http://www.usitc.gov>. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted Inv. No. 337–TA–938 on December 10, 2014, based on a complaint filed by PPC Broadband, Inc. of East Syracuse, New York (“PPC”). 79 FR 73336–37 (Dec. 10, 2014). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain coaxial cable connectors and components thereof and products containing the same by reason of infringement of several claims of United States Patent No. 8,801,448. The notice of investigation named Corning Optical

Communications RF, LLC of Glendale, Arizona (Corning) as respondent. The Office of Unfair Import Investigations is a party to this investigation.

On September 22, 2015, PPC moved to withdraw the complaint and terminate the investigation in its entirety. Corning and the Commission investigative attorney do not oppose the motion.

On September 25, 2015, the ALJ issued the subject ID, granting the motion. The ALJ found that the motion complied with the requirements of Commission Rule 210.21(a)(1) (19 CFR 210.21(a)(1)) and further found that no extraordinary circumstances prohibited granting the motion. None of the parties petitioned for review of the ID.

The Commission has determined not to review the ID.

The authority for the Commission’s determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission’s Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Dated: October 20, 2015.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2015–27100 Filed 10–23–15; 8:45 am]

**BILLING CODE 7020–02–P**

**DEPARTMENT OF LABOR**

**Office of the Secretary**

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Acquisition and Sale of Trust Real Estate Investment Trust Shares by Individual Account Plans Sponsored by Trust Real Estate Investment Trusts**

**ACTION:** Notice.

**SUMMARY:** The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, “Acquisition and Sale of Trust Real Estate Investment Trust Shares by Individual Account Plans Sponsored by Trust Real Estate Investment Trusts,” to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

**DATES:** The OMB will consider all written comments that agency receives on or before November 25, 2015.

**ADDRESSES:** A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=201509-1210-002](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201509-1210-002) (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064, (these are not toll-free numbers) or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-EBSA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202-395-5806 (this is not a toll-free number); or by email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov). Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**FOR FURTHER INFORMATION CONTACT:** Contact Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064, (these are not toll-free numbers) or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**Authority:** 44 U.S.C. 3507(a)(1)(D).

**SUPPLEMENTARY INFORMATION:** This ICR seeks to extend PRA authority for the Acquisition and Sale of Trust Real Estate Investment Trust Shares by Individual Account Plans Sponsored by Trust Real Estate Investment Trusts information collection. Prohibited Transaction Class Exemption 2004-07 permits an individual account pension plan sponsored by a real estate investment trust (REIT) that is organized as a business trust under State law (Trust REIT), or by its affiliates, to purchase, hold and sell publicly traded shares of beneficial interest in the Trust REIT. The relief also covers contributions in kind of REIT shares. Internal Revenue Code of 1986 (Code) section 4975 and Employee Retirement Income Security Act of 1974 (ERISA) section 406 would otherwise prohibit such purchases, holdings, and sales. See 26 U.S.C. 4975 and 29 U.S.C. 1106. The class exemption requires, among other conditions, that the Trust REIT (or its agent) provide the person who has

authority to direct acquisition or sale of REIT shares with the most recent prospectus, quarterly report, and annual report concerning the Trust REIT immediately before an initial investment in the Trust REIT. The person with such authority may be, under the terms of the plan, either an independent fiduciary or a participant exercising investment rights pertaining to his or her individual account under the plan. Updated versions of the reports must be provided to the directing person as subsequently published. The exemption further requires the plan to maintain records concerning investments in a Trust REIT, subject to appropriate confidentiality procedures, for a period of six years and make them available to interested persons including the Department and participants and beneficiaries. The confidentiality procedures must be designed to protect against the possibility that an employer may exert undue influence on participants regarding share-related transactions, and the participants and beneficiaries of the plan must be provided with a statement describing the confidentiality procedures in place and the fiduciary responsible for monitoring these procedures. Code section 4975(c)(2) and ERISA section 408(a) authorize this information collection. See 26 U.S.C. 4975(c)(2) and 29 U.S.C. 1108(a).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210-0124.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on October 31, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice

published in the **Federal Register** on June 17, 2015 (80 FR 34696).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1210-0124. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Agency:* DOL-EBSA.

*Title of Collection:* Acquisition and Sale of Trust Real Estate Investment Trust Shares by Individual Account Plans Sponsored by Trust Real Estate Investment Trusts.

*OMB Control Number:* 1210-0124.

*Affected Public:* Private Sector—businesses or other for-profits.

*Total Estimated Number of Respondents:* 52.

*Total Estimated Number of Responses:* 109,200.

*Total Estimated Annual Time Burden:* 5,469 hours.

*Total Estimated Annual Other Costs Burden:* \$346,000.

Dated: October 20, 2015.

**Michel Smyth,**

*Departmental Clearance Officer.*

[FR Doc. 2015-27119 Filed 10-23-15; 8:45 am]

**BILLING CODE 4510-29-P**

**DEPARTMENT OF LABOR****Occupational Safety and Health Administration**

[Docket No. OSHA–2012–0027]

**The 1,3-Butadiene Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements****AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.**ACTION:** Request for public comments.**SUMMARY:** OSHA solicits public comments concerning its proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the 1,3-Butadiene (BD) Standard (29 CFR 1910.1051).**DATES:** Comments must be submitted (postmarked, sent, or received) by December 28, 2015.**ADDRESSES:***Electronically:* You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.*Facsimile:* If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.*Mail, hand delivery, express mail, messenger, or courier service:* When using this method, you must submit your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2012–0027, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.*Instructions:* All submissions must include the Agency name and the OSHA docket number (OSHA–2012–0027) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at <http://www.regulations.gov>. For further information on submitting comments see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.*Docket:* To read or download comments or other material in thedocket, go to <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the <http://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You also may contact Theda Kenney at the address below to obtain a copy of the ICR.**FOR FURTHER INFORMATION CONTACT:** Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.**SUPPLEMENTARY INFORMATION:****I. Background**

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.*, employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the Paperwork Reduction Act (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The BD Standard requires employers to monitor employee exposure to 1,3-Butadiene; develop and maintain compliance and exposure goal programs if employee exposures to BD are above the Standard's permissible exposure limits or action level; label respirator filter elements to indicate the date and time it is first installed on the respirator; establish medical surveillance programs to monitor employee health, and to

provide employees with information about their exposures and the health effects of exposure to BD.

**II. Special Issues for Comment**

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

**III. Proposed Actions**

OSHA is requesting that the Office of Management and Budget (OMB) extend the approval of the collection of information (paperwork) requirements contained in the 1,3 Butadiene Standard (29 CFR 1910.1051). The Agency is requesting a one hour adjustment (from 916 hours to 915 burden hours). The adjustment is a result of the elimination of the federal access from the burden hour calculation from this ICR.

*Type of Review:* Extension of a currently approved collection.*Title:* The 1,3 Butadiene Standard (29 CFR 1910.1051).*OMB Number:* 1218–0170.*Affected Public:* Business or other for-profits; Not-for-profit organizations; Federal Government; State, Local, or Tribal Government.*Number of Respondents:* 50.*Frequency of Response:* On occasion.*Total Responses:* 3650.*Average Time per Response:* Time per response ranges from 15 seconds (.004 hour) to write the date and time on each new cartridge label to 2 hours to complete a referral medical examination.*Estimated Total Burden Hours:* 915.*Estimated Cost (Operation and Maintenance):* \$112,808.**IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions**

You may submit comments in response to this document as follows:

- (1) Electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal;
- (2) by facsimile; or
- (3) by hard copy. All comments, attachments, and other

material must identify the Agency name and the OSHA docket number for this ICR (Docket No. OSHA–2012–0027). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY) (877) 889–5627).

Comments and submissions are posted without change at <http://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information such as your social security number and date of birth. Although all submissions are listed in the <http://www.regulations.gov> index, some information (e.g., copyrighted material) is not publicly available to read or download from this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <http://www.regulations.gov> Web site to submit comments and access the docket is available at the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available from the Web site, and for assistance in using the Internet to locate docket submissions.

## V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on October 20, 2015.

### David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2015–27065 Filed 10–23–15; 8:45 am]

BILLING CODE 4510–26–P

## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

[Docket No. OSHA–2015–0022]

### Whistleblower Protection Advisory Committee (WPAC)

**AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.

**ACTION:** Announcement of a meeting of WPAC.

**SUMMARY:** WPAC will meet November 10, 2015, in Washington, DC.

**DATES:** *WPAC meeting:* WPAC will meet from 9:00 a.m. to 4:00 p.m., E.T., Tuesday, November 10, 2015.

*Written comments, requests to speak, speaker presentations, and requests for special accommodation:* You must submit (postmark, send, transmit) comments, requests to address the WPAC meeting, speaker presentations (written or electronic), and requests for special accommodations for the WPAC meeting by November 2, 2015.

**ADDRESSES:** *WPAC meeting:* WPAC will meet in Room S–4215 A–C, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

*Submission of comments, requests to speak, and speaker presentations:* You may submit comments, requests to speak at the WPAC meeting, and speaker presentations using one of the following methods:

*Electronically:* You may submit materials, including attachments, electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the on-line instructions for submissions.

*Facsimile (Fax):* If your submission, including attachments, does not exceed 10 pages, you may fax it to the OSHA Docket Office at (202) 693–1648.

*Regular mail, express mail, hand delivery, or messenger (courier) service:* You may submit your materials to the OSHA Docket Office, Docket No. OSHA–2015–0022, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2350 (TTY) (877) 889–5627). OSHA's Docket Office accepts deliveries (hand deliveries, express mail, and messenger service) during normal business hours, 8:15 a.m.–4:45 p.m., E.T., weekdays.

*Requests for special accommodations:* Please submit any requests for special accommodations to attend the WPAC meeting to Ms. Gretta Jameson, OSHA, Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington,

DC 20210; telephone (202) 693–1999; email [jameson.gretta@dol.gov](mailto:jameson.gretta@dol.gov).

*Instructions:* Your submissions must include the agency name and docket number for this **Federal Register** notice (Docket No. OSHA–2015–0022). Due to security-related procedures, submissions by regular mail may experience significant delays. Please contact the OSHA Docket Office for information about security procedures for making submissions. For additional information on submitting comments, requests to speak, and speaker presentations, see the **SUPPLEMENTARY INFORMATION** section of this notice.

### FOR FURTHER INFORMATION CONTACT:

*For press inquiries:* Mr. Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email [meilinger.francis2@dol.gov](mailto:meilinger.francis2@dol.gov).

*For general information about WPAC and WPAC meetings:* Mr. Anthony Rosa, OSHA, Directorate of Whistleblower Protection Programs, Room N–4618, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2199; email [osha.dwpp@dol.gov](mailto:osha.dwpp@dol.gov).

### SUPPLEMENTARY INFORMATION:

#### WPAC Meeting

WPAC will meet Tuesday, November 10, 2015, in Washington, DC. WPAC meetings are open to the public.

The tentative agenda of the WPAC meeting includes:

Remarks from the Assistant Secretary of Labor for Occupational Safety and Health (OSHA);

Remarks from the Director of the Directorate of Whistleblower Protection Programs;

Presentation on State Plan issues;

Public comments;

Work Group discussions/presentations; and,

Old business.

OSHA transcribes WPAC meetings and prepares detailed minutes of the meetings. OSHA places the meeting transcripts and minutes in the public record of the WPAC meeting. The public record also includes Work Group reports, speaker presentations, comments and other materials submitted to WPAC.

#### WPAC Work Group

The Best Practices and Corporate Culture Work Group will meet on November 9, 2015. This work group meeting will be open to the public. The purpose of the work group is to provide recommendations to the full WPAC

committee on issues related to best practices. The work group may report to WPAC at the November 10, 2015 meeting for discussion by the full committee. The work group will meet from 1:00 p.m. to 4:00 p.m. on November 9, 2015 in S-4215 A-C in the Francis Perkins Building.

For additional information on WPAC work group meetings or participating in them, please contact Mr. Rosa or look on the WPAC page on OSHA's Web page at <http://www.whistleblowers.gov>.

#### Public Participation, Submissions, and Access to Public Record

**WPAC meetings:** All WPAC meetings are open to the public. Individuals attending meetings at the U.S. Department of Labor must enter the building at the visitors' entrance, 3rd and C Streets NW., and pass through building security. Attendees must have valid government-issued photo identification (such as a driver's license) to enter the building. For additional information about building security measures for attending WPAC meetings, please contact Ms. Jameson (see **ADDRESSES** section).

Individuals needing special accommodations to attend the WPAC meeting should contact Ms. Jameson as well.

**Submission of written comments:** You may submit written comments using one of the methods identified in the **ADDRESSES** section. Your submissions must include the Agency name and docket number for this WPAC meeting (Docket No. OSHA-2015-0022). OSHA will provide copies of submissions to WPAC members.

Because of security-related procedures, submissions by regular mail may experience significant delays. For information about security procedures for submitting materials by hand delivery, express mail, and messenger or courier service, please contact the OSHA Docket Office (see **ADDRESSES** section).

**Requests to speak and speaker presentations:** If you want to address WPAC at the meeting, you must submit your request to speak, as well as any written or electronic presentation, by November 2, 2015, using one of the methods listed in the **ADDRESSES** section. Your request must state:

- The amount of time requested to speak;
- The interest you represent (e.g., business, organization, affiliation), if any; and
- A brief outline of your presentation.

The WPAC Chair may grant requests to address WPAC as time and circumstances permit.

**Public docket of the WPAC meeting:** OSHA will place comments, requests to speak, and speaker presentations, including any personal information you provide, in the public docket of this WPAC meeting without change, and those documents may be available online at <http://www.regulations.gov>. Therefore, OSHA cautions you about submitting personal information, such as Social Security numbers and birthdates.

OSHA also places in the public docket the meeting transcript, meeting minutes, documents presented at the WPAC meeting, and other documents pertaining to the WPAC meeting. These documents are available online at <http://www.regulations.gov> under Docket No. OSHA-2015-0022.

**Access to the public record of WPAC meetings:** To read or download documents in the public docket of this WPAC meeting, go to Docket No. OSHA-2015-0022 at <http://www.regulations.gov>. The <http://www.regulations.gov> index also lists all documents in the public record for this meeting; however, some documents (e.g., copyrighted materials) are not publicly available through that Web page. All documents in the public record, including materials not available through <http://www.regulations.gov>, are available for inspection and copying in the OSHA Docket Office (see **ADDRESSES** section). Please contact the OSHA Docket Office for assistance in making submissions to, or obtaining materials from, the public docket.

Electronic copies of this **Federal Register** notice are available at <http://www.regulations.gov>. This notice, as well as news releases and other relevant information, also are available on the Directorate of Whistleblower Protections Programs Web page at <http://www.whistleblowers.gov>.

#### Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice under the authority granted by 5 U.S.C. App. 2, 41 CFR part 102-3, chapter 1600 of Department of Labor Management Series 3 (Aug. 15, 2013), 77 FR 3912 (Jan. 25, 2012), and the Secretary of Labor's authority to administer the whistleblower provisions found in 29 U.S.C. 660(c), 49 U.S.C. 31105, 15 U.S.C. 2651, 46 U.S.C. 80507, 42 U.S.C. 300j-9(i), 33 U.S.C. 1367, 15 U.S.C. 2622, 42 U.S.C. 6971, 42 U.S.C. 7622, 42 U.S.C. 9610, 42 U.S.C. 5851, 49 U.S.C. 42121, 18 U.S.C. 1514A, 49 U.S.C. 60129, 49 U.S.C. 20109, 6 U.S.C. 1142,

15 U.S.C. 2087, 29 U.S.C. 218c, 12 U.S.C. 5567, 46 U.S.C. 2114, 21 U.S.C. 399d, and 49 U.S.C. 30171.

Signed at Washington, DC, on October 21, 2015.

**David Michaels,**

*Assistant Secretary of Labor for Occupational Safety and Health.*

[FR Doc. 2015-27136 Filed 10-23-15; 8:45 am]

**BILLING CODE 4510-26-P**

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#### LEGAL SERVICES CORPORATION

#### Notice of Intent To Award—Grant Awards for the Provision of Civil Legal Services to Eligible Low-Income Clients Beginning January 1, 2016

**AGENCY:** Legal Services Corporation.

**ACTION:** Announcement of intention to make FY 2016 Competitive Grant Awards.

**SUMMARY:** The Legal Services Corporation (LSC) hereby announces its intention to award grants and contracts to provide economical and effective delivery of high quality civil legal services to eligible low-income clients, beginning January 1, 2016.

**DATES:** All comments and recommendations must be received on or before the close of business on November 25, 2015.

**ADDRESSES:** Legal Services Corporation—Competitive Grants, Legal Services Corporation; 3333 K Street NW., Third Floor; Washington, DC 20007.

**FOR FURTHER INFORMATION CONTACT:** Reginald Haley, Office of Program Performance, at (202) 295-1545, or [haley@lsc.gov](mailto:haley@lsc.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to LSC's announcement of funding availability on March 27, 2015, 80 FR 16461, and Grant Renewal applications due beginning June 1, 2015, LSC intends to award funds to provide civil legal services in the indicated service areas. Applicants for each service area are listed below. The amounts below reflect the funding amounts for 2015 grant awards to each service area. These amounts will change based on the 2016 census adjustment and the final FY2016 appropriation.

LSC will post all updates and/or changes to this notice at <http://www.grants.lsc.gov/grants-grantee-resources>. Interested parties are asked to visit <http://www.grants.lsc.gov/grants-grantee-resources> regularly for updates on the LSC competitive grants process.



Name of applicant organization	State	Service area	Estimated annualized 2016 funding
Alaska Legal Services .....	AK	AK-1 .....	\$ 659,864
Alaska Legal Services .....	AK	NAK-1 .....	542,139
Legal Services Alabama .....	AL	AL-4 .....	5,972,421
Center For Arkansas Legal Services .....	AR	AR-7 .....	2,183,008
Legal Aid of Arkansas .....	AR	AR-6 .....	1,495,419
American Samoa Legal Aid .....	AS	AS-1 .....	222,147
Community Legal Services .....	AZ	AZ-3 .....	5,017,450
Community Legal Services .....	AZ	MAZ .....	148,510
DNA-People's Legal Services .....	AZ	AZ-2 .....	428,253
DNA-People's Legal Services .....	AZ	NAZ-5 .....	2,615,849
Southern Arizona Legal Aid .....	AZ	AZ-5 .....	2,121,481
Southern Arizona Legal Aid .....	AZ	NAZ-6 .....	638,976
Bay Area Legal Aid .....	CA	CA-28 .....	4,203,084
California Indian Legal Services .....	CA	CA-1 .....	24,492
California Indian Legal Services .....	CA	NCA-1 .....	885,652
California Rural Legal Assist .....	CA	CA-31 .....	4,766,159
California Rural Legal Assist .....	CA	MCA .....	2,640,544
Central California Legal Services .....	CA	CA-26 .....	2,838,996
Greater Bakersfield Legal Assist .....	CA	CA-2 .....	1,018,963
Inland Counties Legal Services .....	CA	CA-12 .....	4,676,508
Legal Aid Society of Orange County .....	CA	CA-19 .....	3,514,880
Legal Aid Society of San Diego .....	CA	CA-14 .....	2,793,238
Legal Aid Foundation of Los Angeles .....	CA	CA-29 .....	5,746,726
Legal Services of Northern California .....	CA	CA-27 .....	3,650,471
Neighborhood Legal Services of Los Angeles County .....	CA	CA-30 .....	3,767,240
Colorado Legal Services .....	CO	CO-6 .....	4,402,360
Colorado Legal Services .....	CO	MCO .....	148,559
Colorado Legal Services .....	CO	NCO-1 .....	96,270
Pine Tree Legal Assistance .....	CT	NCT-1 .....	15,693
Statewide Legal Services of Connecticut .....	CT	CT-1 .....	2,430,737
Neighborhood Legal Services Program of the District of Columbia .....	DC	DC-1 .....	754,494
Legal Aid Bureau .....	DE	MDE .....	24,834
Legal Services Corporation of Delaware .....	DE	DE-1 .....	689,992
Bay Area Legal Services .....	FL	FL-16 .....	3,274,589
Coast To Coast Legal Aid of So. Florida .....	FL	FL-18 .....	1,959,338
Community Legal Services of Mid-Florida .....	FL	FL-15 .....	4,086,748
Florida Rural Legal Services .....	FL	FL-17 .....	3,759,690
Florida Rural Legal Services .....	FL	MFL .....	898,346
Legal Services of Greater Miami .....	FL	FL-5 .....	3,221,428
Legal Services of North Florida .....	FL	FL-13 .....	1,512,808
Three Rivers Legal Services .....	FL	FL-14 .....	2,028,848
Atlanta Legal Aid Society .....	GA	GA-1 .....	3,669,473
Georgia Legal Services Program .....	GA	GA-2 .....	7,713,271
Georgia Legal Services Program .....	GA	MGA .....	392,175
Guam Legal Services .....	GU	GU-1 .....	250,355
Legal Aid Society of Hawaii .....	HI	HI-1 .....	1,213,720
Legal Aid Society of Hawaii .....	HI	NHI-1 .....	229,627
Iowa Legal Aid .....	IA	MIA .....	37,740
Iowa Legal Aid .....	IA	IA-3 .....	2,506,246
Idaho Legal Aid Services .....	ID	ID-1 .....	1,460,374
Idaho Legal Aid Services .....	ID	MID .....	186,963
Idaho Legal Aid Services .....	ID	NID-1 .....	65,127
LAF (Legal Assist Foundation. Metro. Chicago) .....	IL	IL-6 .....	5,804,915
LAF (Legal Assist Foundation. Metro. Chicago) .....	IL	MIL .....	249,699
Land of Lincoln Legal Assist. Foundation .....	IL	IL-3 .....	2,511,505
Prairie State Legal Services .....	IL	IL-7 .....	3,650,736
Indiana Legal Services .....	IN	IN-5 .....	6,558,725
Indiana Legal Services .....	IN	MIN .....	113,731
Kansas Legal Services .....	KS	KS-1 .....	2,623,776
Appalachian Res. & Def. Fund of Kentucky .....	KY	KY-5 .....	1,534,297
Kentucky Legal Aid .....	KY	KY-9 .....	1,140,900
Legal Aid of The Blue Grass .....	KY	KY-10 .....	1,479,070
Legal Aid Society .....	KY	KY-2 .....	1,324,022
Acadiana Legal Services Corp .....	LA	LA-10 .....	1,471,883
Legal Services of North Louisiana .....	LA	LA-11 .....	1,415,964
Southeast Louisiana Legal Services Corporation .....	LA	LA-13 .....	2,845,567
Community Legal Aid .....	MA	MA-10 .....	1,399,287
Northeast Legal Aid .....	MA	MA-4 .....	774,370
South Coastal Counties Legal Services .....	MA	MA-12 .....	860,641
Volunteer Lawyers Project of the Boston Bar .....	MA	MA-11 .....	1,902,693
Legal Aid Bureau .....	MD	MD-1 .....	3,725,595
Legal Aid Bureau .....	MD	MMD .....	90,943



Name of applicant organization	State	Service area	Estimated annualized 2016 funding
Pine Tree Legal Assistance .....	ME	ME-1 .....	1,104,061
Pine Tree Legal Assistance .....	ME	MMX-1 .....	124,933
Pine Tree Legal Assistance .....	ME	NME-1 .....	64,612
Pending receipt and review of grant proposals <sup>1</sup> .....	MI	MI-13 .....	4,368,810
Legal Aid of Western Michigan .....	MI	MI-15 .....	2,217,766
Legal Services of Eastern Michigan .....	MI	MI-14 .....	1,626,693
Legal Services of Northern Michigan .....	MI	MI-9 .....	815,225
Michigan Advocacy Program .....	MI	MI-12 .....	1,637,057
Michigan Advocacy Program .....	MI	MMI .....	602,101
Michigan Indian Legal Services .....	MI	NMI-1 .....	165,020
Anishinabe Legal Services .....	MN	NMN-1 .....	239,566
Cent Minnesota Legal Services .....	MN	MN-6 .....	1,675,663
Legal Aid Serv. of N.E. Minn .....	MN	MN-1 .....	439,057
Legal Services of Northwest Minnesota Corp .....	MN	MN-4 .....	336,144
S. Minn. Regional Legal Services .....	MN	MMN .....	200,128
S. Minn. Regional Legal Services .....	MN	MN-5 .....	1,547,664
Legal Aid of Western Missouri .....	MO	MMO .....	81,487
Legal Aid of Western Missouri .....	MO	MO-3 .....	1,939,623
Legal Services of Eastern Missouri .....	MO	MO-4 .....	1,999,642
Legal Services of Southern Missouri .....	MO	MO-7 .....	1,690,050
Mid-Missouri Legal Services Corporation .....	MO	MO-5 .....	445,273
Micronesian Legal Services .....	MP	MP-1 .....	1,255,539
Mississippi Center For Legal Services .....	MS	MS-10 .....	2,653,869
Mississippi Center For Legal Services .....	MS	NMS-1 .....	83,330
North Mississippi Rural Legal Services .....	MS	MS-9 .....	1,747,289
Montana Legal Services Association .....	MT	MMT .....	54,599
Montana Legal Services Association .....	MT	MT-1 .....	953,302
Montana Legal Services Association .....	MT	NMT-1 .....	159,616
Legal Aid of North Carolina .....	NC	MNC .....	536,104
Legal Aid of North Carolina .....	NC	NC-5 .....	10,616,211
Legal Aid of North Carolina .....	NC	NNC-1 .....	218,781
Legal Services of North Dakota .....	ND	ND-3 .....	447,577
Legal Services of North Dakota .....	ND	NND-3 .....	270,032
Southern MN Regional Legal Services .....	ND	MND .....	115,945
Legal Aid of Nebraska .....	NE	MNE .....	42,294
Legal Aid of Nebraska .....	NE	NE-4 .....	1,524,974
Legal Aid of Nebraska .....	NE	NNE-1 .....	33,135
Legal Advice & Referral Center .....	NH	NH-1 .....	742,908
Central Jersey Legal Services .....	NJ	NJ-17 .....	1,095,631
Essex-Newark Legal Services Project .....	NJ	NJ-8 .....	831,986
Legal Services of Northwest Jersey .....	NJ	NJ-15 .....	389,039
Northeast New Jersey Legal Services .....	NJ	NJ-18 .....	1,632,392
South Jersey Legal Services .....	NJ	MNJ .....	120,687
South Jersey Legal Services .....	NJ	NJ-12 .....	681,325
South Jersey Legal Services .....	NJ	NJ-16 .....	1,247,913
DNA-People's Legal Services .....	NM	NM-1 .....	189,219
DNA-People's Legal Services .....	NM	NNM-2 .....	22,773
New Mexico Legal Aid .....	NM	MNM .....	87,360
New Mexico Legal Aid .....	NM	NM-5 .....	2,568,653
New Mexico Legal Aid .....	NM	NNM-4 .....	465,776
Nevada Legal Services .....	NV	NNV-1 .....	133,300
Nevada Legal Services .....	NV	NV-1 .....	2,689,598
Legal Aid Society of Mid-New York .....	NY	MNY .....	276,872
Legal Aid Society of Mid-New York .....	NY	NY-22 .....	1,586,522
Legal Aid Society of Northeastern New York .....	NY	NY-21 .....	1,235,643
Legal Assistance of Western New York .....	NY	NY-23 .....	1,668,875
Legal Services of The Hudson Valley .....	NY	NY-20 .....	1,623,879
Legal Services For New York City .....	NY	NY-9 .....	11,120,280
Nassau/Suffolk Law Services .....	NY	NY-7 .....	1,162,634
Neighborhood Legal Services .....	NY	NY-24 .....	1,194,326
Community Legal Aid Services .....	OH	OH-20 .....	1,942,738
Legal Aid of Western Ohio .....	OH	MOH .....	126,002
Legal Aid of Western Ohio .....	OH	OH-23 .....	3,018,102
Legal Aid Society of Cleveland .....	OH	OH-21 .....	2,180,522
Legal Aid Society of Greater Cincinnati .....	OH	OH-18 .....	1,640,696
Ohio State Legal Services .....	OH	OH-24 .....	3,505,040
Legal Aid Services of Oklahoma .....	OK	MOK .....	62,596
Legal Aid Services of Oklahoma .....	OK	OK-3 .....	4,213,616
Oklahoma Indian Legal Services .....	OK	NOK-1 .....	820,795
Legal Aid Services of Oregon .....	OR	MOR .....	557,181
Legal Aid Services of Oregon .....	OR	NOR-1 .....	185,053
Legal Aid Services of Oregon .....	OR	OR-6 .....	3,596,884

Name of applicant organization	State	Service area	Estimated annualized 2016 funding
Laurel Legal Services .....	PA	PA-5 .....	632,369
Legal Aid of Southeastern Pennsylvania .....	PA	PA-23 .....	1,111,687
MidPenn Legal Services .....	PA	PA-25 .....	2,309,547
Neighborhood Legal Services Association .....	PA	PA-8 .....	1,396,409
North Penn Legal Services .....	PA	PA-24 .....	1,850,007
Northwestern Legal Services .....	PA	PA-26 .....	696,354
Philadelphia Legal Assist. Center .....	PA	MPA .....	165,788
Philadelphia Legal Assist. Center .....	PA	PA-1 .....	2,738,694
Southwestern Pennsylvania Legal Services .....	PA	PA-11 .....	421,409
Community Law Office .....	PR	PR-2 .....	221,282
Puerto Rico Legal Services .....	PR	MPR .....	290,819
Puerto Rico Legal Services .....	PR	PR-1 .....	11,127,089
Rhode Island Legal Services .....	RI	RI-1 .....	950,613
South Carolina Legal Services .....	SC	MSC .....	197,851
South Carolina Legal Services .....	SC	SC-8 .....	5,504,311
Dakota Plains Legal Services .....	SD	NSD-1 .....	935,989
Dakota Plains Legal Services .....	SD	SD-4 .....	385,715
East River Legal Services .....	SD	SD-2 .....	385,575
Legal Aid Society of Middle TN and the Cumberlands .....	TN	TN-10 .....	3,077,716
Legal Aid of East Tennessee .....	TN	TN-9 .....	2,408,494
Memphis Area Legal Services .....	TN	TN-4 .....	1,421,775
West Tennessee Legal Services .....	TN	TN-7 .....	693,812
Legal Aid of Northwest Texas .....	TX	TX-14 .....	8,649,058
Lone Star Legal Aid .....	TX	TX-13 .....	10,283,901
Texas RioGrande Legal Aid .....	TX	MSX-2 .....	1,692,033
Texas RioGrande Legal Aid .....	TX	NTX-1 .....	31,374
Texas RioGrande Legal Aid .....	TX	TX-15 .....	10,260,847
Utah Legal Services .....	UT	MUT .....	67,848
Utah Legal Services .....	UT	NUT-1 .....	82,473
Utah Legal Services .....	UT	UT-1 .....	2,346,659
Blue Ridge Legal Services .....	VA	VA-19 .....	784,252
Central Virginia Legal Aid Society .....	VA	MVA .....	157,757
Central Virginia Legal Aid Society .....	VA	VA-18 .....	1,111,038
Legal Aid Society of Eastern Virginia .....	VA	VA-16 .....	1,145,838
Legal Services of Northern Virginia .....	VA	VA-20 .....	1,254,701
Southwest Virginia Legal Aid Society .....	VA	VA-15 .....	716,020
Virginia Legal Aid Society .....	VA	VA-17 .....	850,074
Legal Services of The Virgin Islands .....	VI	VI-1 .....	164,978
Legal Services Law Line of Vermont .....	VT	VT-1 .....	486,833
Northwest Justice Project .....	WA	MWA .....	730,121
Northwest Justice Project .....	WA	NWA-1 .....	285,566
Northwest Justice Project .....	WA	WA-1 .....	5,393,583
Legal Action of Wisconsin .....	WI	MWI .....	91,069
Legal Action of Wisconsin .....	WI	WI-5 .....	3,886,718
Wisconsin Judicare .....	WI	NWI-1 .....	155,502
Wisconsin Judicare .....	WI	WI-2 .....	1,024,320
Legal Aid of West Virginia .....	WV	WV-5 .....	2,253,495
Legal Aid of Wyoming .....	WY	WY-4 .....	416,828
Legal Aid of Wyoming .....	WY	NWY-1 .....	173,227

<sup>1</sup> LSC re-competed the MI-13 service area in Michigan on September 22, 2015. Grant proposals are due October 23, 2015. LSC will publish the notice of intent to award funding for the MI-13 service area in November 2015.

These grants will be awarded under the authority conferred on LSC by Section 1006(a)(1) of the Legal Services Corporation Act, 42 U.S.C. 2996e(a)(1). Awards will be made so that each service area is served, although no listed organization is guaranteed an award or contract. Grants will become effective and grant funds will be distributed on or about January 1, 2016.

This notice is issued pursuant to 42 U.S.C. 2996g(e). Comments and recommendations concerning potential grantees are invited, and should be delivered to LSC within thirty (30) days

from the date of publication of this notice.

Dated: October 21, 2015.

**Stefanie K. Davis,**

*Assistant General Counsel.*

[FR Doc. 2015-27140 Filed 10-23-15; 8:45 am]

**BILLING CODE 7050-01-P**

## OFFICE OF MANAGEMENT AND BUDGET

### Draft 2015 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities

**AGENCY:** Office of Management and Budget, Executive Office of the President.

**ACTION:** Notice of availability and request for comments.

**SUMMARY:** The Office of Management and Budget (OMB) requests comments on its Draft 2015 Report to Congress on

the Benefits and Costs of Federal Regulations, available at: [http://www.whitehouse.gov/omb/inforeg\\_regpol\\_reports\\_congress/](http://www.whitehouse.gov/omb/inforeg_regpol_reports_congress/). The Draft Report is divided into three chapters. Chapter I examines the benefits and costs of major Federal regulations issued in fiscal year 2014 and summarizes the benefits and costs of major regulations issued between October 2004 and September 2014. It also discusses regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Chapter II offers recommendations for regulatory reform. Chapter III summarizes agency compliance with the Unfunded Mandates Reform Act.

OMB requests that comments be submitted electronically to OMB by December 21, 2015 through [www.regulations.gov](http://www.regulations.gov).

**DATES:** To ensure consideration of comments as OMB prepares this Draft Report for submission to Congress, comments must be in writing and received by December 21, 2015.

**ADDRESSES:** Submit comments by one of the following methods:

- [www.regulations.gov](http://www.regulations.gov): Direct comments to Docket ID OMB-2014-0002.

- *Fax:* (202) 395-5806.

- *Mail:* Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: Mabel Echols, NEOB, Room 10102, 725 17th Street NW., Washington, DC 20503. To ensure that your comments are received, we recommend that comments on this draft report be electronically submitted.

All comments and recommendations submitted in response to this notice will be made available to the public, including by posting them on OMB's Web site. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means OMB will not know your identity or contact information unless you provide it in the body of your comment. For further information, contact: Office of Information and Regulatory Affairs, Office of Management and Budget, NEOB, Room 10102, 725 17th Street NW., Washington, DC 20503. Telephone: (202) 395-5897.

**SUPPLEMENTARY INFORMATION:** Congress directed the Office of Management and Budget (OMB) to prepare an annual Report to Congress on the Costs and Benefits of Federal Regulations. Specifically, Section 624 of the FY 2001 Treasury and General Government

Appropriations Act, also known as the "Regulatory Right-to-Know Act," (the Act) requires OMB to submit a report on the costs and benefits of Federal regulations together with recommendations for reform. The Act states that the report should contain estimates of the costs and benefits of regulations in the aggregate, by agency and agency program, and by major rule, as well as an analysis of impacts of Federal regulation on State, local, and tribal governments, small businesses, wages, and economic growth. The Act also states that the report should be subject to notice and comment and peer review.

**Howard Shelanski,**

*Administrator, Office of Information and Regulatory Affairs.*

[FR Doc. 2015-27163 Filed 10-23-15; 8:45 am]

**BILLING CODE 3110-01-P**

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## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (15-092)]

### Notice of Centennial Challenges 2016 Sample Return Robot (SRR) Challenge

**AGENCY:** National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of Centennial Challenges 2016 Sample Return Robot (SRR) Challenge.

**SUMMARY:** This notice is issued in accordance with 51 U.S.C. 20144(c). The Sample Return Robot (SRR) Challenge is scheduled and teams that wish to compete may now register. Centennial Challenges is a program of prize competitions to stimulate innovation in technologies of interest and value to NASA and the nation. The 2016 SRR Challenge is a prize competition designed to encourage development of new technologies or application of existing technologies in unique ways to autonomously collect and retrieve samples using robotics. NASA is providing the prize purse and Worcester Polytechnic Institute (WPI) is conducting the challenge.

**DATES:** 2016 SRR Challenge for Level 1 will be held June 6-11, 2016; Level 2 will be held September 1-5, 2016.

**ADDRESSES:** 2016 SRR Challenge will be conducted at Worcester Polytechnic Institute near Worcester, Massachusetts.

**FOR FURTHER INFORMATION CONTACT:** To register for or get additional information regarding the 2016 SRR Challenge, please visit: <http://www.nasa.gov/robotprize>.

For general information on the NASA Centennial Challenges Program please

visit: <http://www.nasa.gov/challenges>. General questions and comments regarding the program should be addressed to Monsi Roman, Centennial Challenges Program, NASA Marshall Space Flight Center Huntsville, AL 35812. Email address: [hq-stmd-centennialchallenges@mail.nasa.gov](mailto:hq-stmd-centennialchallenges@mail.nasa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Summary

Autonomous robot rovers will seek out samples and return them to a designated point in a set time period. Samples will be randomly placed throughout the roving area. They may be placed close to obstacles, both movable and immovable. Robots will be required to navigate over unknown terrain, around obstacles, and in varied lighting conditions to identify, retrieve, and return these samples. Winners will be determined based on the number of samples returned to the designated collection point as well as the value assigned to the samples.

##### I. Prize Amounts

The total Sample Return Robot Challenge purse is \$1,500,000 (one million five hundred thousand U.S. dollars). Prizes will be offered for entries that meet specific requirements detailed in the Rules.

##### II. Eligibility

To be eligible to win a prize, competitors must:

- (1) Register and comply with all requirements in the rules.

- (2) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.

- (3) Not be a Federal entity or Federal employee acting within the scope of their employment.

##### III. Rules

The complete rules and team agreement for the 2016 SRR Challenge can be found at: <http://wp.wpi.edu/challenge/>

**Cheryl E. Parker,**

*Federal Register Liaison Officer.*

[FR Doc. 2015-27118 Filed 10-23-15; 8:45 am]

**BILLING CODE 7510-13-P**

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## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

### Notice of Information Collection

**AGENCY:** National Aeronautics and Space Administration (NASA).

*Notice:* (15–091).

**ACTION:** Notice of information collection.

**SUMMARY:** The National Aeronautics and Space Administration, 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 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

**DATES:** All comments should be submitted within 30 calendar days from the date of this publication.

**ADDRESSES:** Interested persons are invited to submit written comments regarding the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 7th Street NW., Washington DC 20543. Attention: Desk Officer for NASA.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Frances Teel, NASA PRA Clearance Officer, NASA Headquarters, 300 E Street SW., Mail Code JF000, Washington, DC 20546, or [Frances.C.Teel@NASA.gov](mailto:Frances.C.Teel@NASA.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Abstract**

NASA promotes activities to demonstrate innovative uses and practical benefits of NASA Earth science data, scientific knowledge, and technology. NASA's Applied Sciences Program established the DEVELOP National Program to research environmental management and public policy issues at the state and local level. Under the guidance of NASA and partner organization science advisors, DEVELOP enables participants to lead research projects that utilize NASA Earth observations to address community concerns and public policy issues. Through teams, DEVELOP participants gain experience by (1) utilizing NASA's Earth Science satellite and airborne resources, to include remote sensing and geographic information systems (GIS), and (2) communicating research results. DEVELOP projects serve the global community and extend NASA Earth Science research and technology to benefit society. A focus on both professional and personal development is central to DEVELOP's ten week sessions, which are conducted annually during the spring, summer, and fall.

The DEVELOP research opportunity is available to individuals 18 years and older and includes transitioning career professionals (including veterans of the Armed Forces), recent college/university graduates, and currently enrolled students. Information is collected through an online process from individuals interested in participating in the NASA DEVELOP Program for a ten week session. Information collected from individuals includes a completed application, academic transcript, resume, and two letters of recommendation references per applicant.

With the growing societal role of science and technology in today's global workplace, DEVELOP is fostering an adept corps of tomorrow's scientists and leaders.

**II. Method of Collection**

Electronic.

**III. Data**

*Title:* DEVELOP National Program Application.

*OMB Number:* 2700–XXXX.

*Type of review:* Existing collection in use without an OMB Control Number.

*Affected Public:* Individuals.

*Estimated Number of Respondents:* 2,850.

*Estimated Time per Response:* Variable.

*Estimated Total Annual Burden Hours:* 2,100.

*Estimated Total Annual Cost to Respondents:* \$37,275.

**IV. Request for Comments**

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (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 automated collection techniques or the use of other forms of information technology.

**Frances Teel,**  
NASA PRA Clearance Officer.

[FR Doc. 2015–27108 Filed 10–23–15; 8:45 am]

**BILLING CODE 7510–13–P**

**NATIONAL SCIENCE FOUNDATION**

**Advisory Committee for Mathematical and Physical Sciences; Notice of Meeting**

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

*Name:* Advisory Committee for Mathematical and Physical Sciences (#66)

*Date/Time:* November 5, 2015: 8:00 a.m. to 6:30 p.m. November 6, 2015: 8:00 a.m. to 1:00 p.m.

*Place:* National Science Foundation, 4201 Wilson Boulevard, Suite 375, Arlington, Virginia 22230

*Type of Meeting:* Open.

*Contact Person:* Eduardo Misawa, National Science Foundation, 4201 Wilson Boulevard, Suite 505, Arlington, Virginia 22203; Telephone: 703/292–8300

*Purpose of Meeting:* To provide advice, recommendations and counsel on major goals and policies pertaining to mathematical and physical sciences programs and activities.

**Agenda**

*Thursday, November 5th, 2015 8:00 a.m.–6:30 p.m.*

8:00—Registration and refreshments

8:30—Meeting opening

9:00—Science Hors d'oeuvres

9:30—MPS updates

10:00—Break

10:15—Updates on NSF initiative:

INCLUDES *Inclusion across the Nation of Communities of Learners that have been Underrepresented for Diversity in Engineering and Science*

11:00—Graduate Student Training

12:00—Lunch

12:45—Updates on NSF initiative:

INFEWS *Innovations at the Nexus of Food, Energy, and Water Systems*

1:15—Update on Partnerships

1:45—Update on Public Access

2:15—Division of Materials Research Committee of Visitors (COV) Report

3:00—Break

3:15—Robust and reliable science

4:00—National Strategic Computing Initiative (NSCI) briefing

4:45—Cross-Directorate Advisory Committees updates

5:45—Preparation for meeting with NSF Director

6:30—Break for the day

*Friday, November 6th, 2015 8:00 a.m.–1:00 p.m.*

8:00—Registration and refreshments

8:30—Meeting opening

9:00—Meeting with NSF Director  
 10:00—Break  
 10:15—Broader Impacts  
 11:15—Discussions  
 1:00—Meeting Adjourn

Dated: October 20, 2015.

**Crystal Robinson,**

*Committee Management Officer.*

[FR Doc. 2015-27057 Filed 10-23-15; 8:45 am]

BILLING CODE 7555-01-P

## NUCLEAR REGULATORY COMMISSION

[NRC-2015-0033]

### Information Collection: Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of submission to the Office of Management and Budget; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.”

**DATES:** Submit comments by November 25, 2015.

**ADDRESSES:** Submit comments directly to the OMB reviewer at: Vlad Dorjets, Desk Officer, Office of Information and Regulatory Affairs (3150-0214) NEOB-10202, Office of Management and Budget, Washington, DC 20503; telephone: 202-395-7315, email: [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

**FOR FURTHER INFORMATION CONTACT:** Tremaine Donnell, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6258; email: [INFOCOLLECTS.Resource@nrc.gov](mailto:INFOCOLLECTS.Resource@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Obtaining Information and Submitting Comments

##### A. Obtaining Information

Please refer to Docket ID NRC-2015-0033 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2015-0033.
- *NRC’s Agencywide Documents Access and Management System*

(ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The supporting statement and burden estimates are available in ADAMS under Accession ML15266A262 and ML15266A263, respectively.

- *NRC’s PDR:* You may examine and purchase copies of public documents at the NRC’s PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC’s Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC’s Clearance Officer, Tremaine Donnell, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6258; email: [INFOCOLLECTS.Resource@NRC.GOV](mailto:INFOCOLLECTS.Resource@NRC.GOV).

##### B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

#### II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.” The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is

not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on June 23, 2015, 80 FR 35995.

1. *The title of the information collection:* 10 CFR part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.

2. *OMB approval number:* 3150-0214.

3. *Type of submission:* Extension.

4. *The form number if applicable:* Standard Fingerprint Form, FD-258.

5. *How often the collection is required or requested:* One time for initial compliance notifications and fingerprints for the reviewing officials; and as needed for implementation notifications, event notifications, notifications of shipments of radioactive material, and fingerprinting of new employees.

6. *Who will be required or asked to respond:* Licensees that are authorized to possess and use category 1 or category 2 quantities of radioactive material.

7. *The estimated number of annual responses:* 103,983.

8. *The estimated number of annual respondents:* 1,500 (300 NRC Licensees + 1,200 Agreement State Licensees).

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 138,570.2 hours (1,932.4 hours reporting + 85,644.2 hours recordkeeping + 50,993.6 hours third-party disclosure).

10. *Abstract:* Part 37 of title 10 of the *Code of Federal Regulations* (10 CFR), contains security requirements for the use of category 1 and category 2 quantities of radioactive material. Licensees are required to: (1) Develop procedures for implementation of the security provisions; (2) develop a security plan that describes how security is being implemented; (3) conduct training on the procedures and security plan; (4) conduct background investigations for those individuals permitted access to category 1 or category 2 quantities of radioactive material; (5) coordinate with LLEAs so the LLEAs would be better prepared to respond in an emergency; (6) conduct preplanning and coordination activities before shipping radioactive material; and (7) implement security measures for the protection of the radioactive material. Licensees are required to promptly report any attempted or actual theft or diversion of the radioactive material. Licensees are required to keep copies of the security plan, procedures, background investigation records,

training records, and documentation that certain activities have occurred. The NRC uses the information required by 10 CFR part 37 to fulfill its responsibilities to respond to, investigate, and correct situations that adversely affect public health and safety or the common defense and security.

Dated at Rockville, Maryland, this 20th day of October 2015.

For the Nuclear Regulatory Commission.

**Kristen Benney,**

*Acting NRC Clearance Officer, Office of Information Services.*

[FR Doc. 2015-27063 Filed 10-23-15; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

[NRC-2015-0099]

### Sizing of Large Lead-Acid Storage Batteries

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Regulatory guide; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 1 of Regulatory Guide (RG) 1.212, "Sizing of Large Lead-Acid Storage Batteries." This RG endorses, with certain clarifications, the Institute of Electrical and Electronic Engineers (IEEE) Standard 485-2010, "IEEE Recommended Practice for Sizing Lead-Acid Batteries for Stationary Applications." This RG describes methods acceptable to the NRC for complying with the design requirements for vented lead-acid batteries used in stationary applications under full float operation for nuclear power plants.

**ADDRESSES:** Please refer to Docket ID NRC-2015-0099 when contacting the NRC about the availability of information regarding this document. You may obtain publically-available information related to this document, using the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2015-0099. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Document collection at <http://www.nrc.gov/reading-rm/>

*adams.html*. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. Revision 1 of RG 1.212, is available in ADAMS under Accession No. ML15170A003. The regulatory analysis may be found in ADAMS under Accession No. ML14031A264.

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

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

#### FOR FURTHER INFORMATION CONTACT:

Liliana Ramadan, email, [Liliana.Ramadan@nrc.gov](mailto:Liliana.Ramadan@nrc.gov), telephone: 301-415-2463; or Mark Orr, email, [Mark.Orr@nrc.gov](mailto:Mark.Orr@nrc.gov), telephone: 301.415.6003. Both of the Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

The NRC is issuing a revision to an existing guide in the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses. Revision 1 of RG 1.212 was issued with a temporary identification as Draft Regulatory Guide, DG-1311. This RG is being updated to provide guidance to applicants and licensees for defining the direct current load and size of vented lead acid batteries for full float stationary applications to support nuclear power plant operations.

##### II. Additional Information

DG-1311 was published in the **Federal Register** on April 20, 2015 (80 FR 21774) for a 60-day public comment period. The public comment period closed on June 19, 2015, and no comments were received.

### III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801-808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

### IV. Backfitting and Issue Finality

This RG provides guidance to applicants and licensees for defining the direct current load and size of lead-acid batteries needed to supply the defined load for full float stationary applications to support nuclear power plant operations. This RG does not constitute backfitting as defined in § 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR) (the Backfit Rule), and is not otherwise inconsistent with the issue finality provisions in 10 CFR part 52, "Licenses, Certifications and Approvals for Nuclear Power Plants." As discussed in the "Implementation" section of the RG, the NRC has no current intention to impose this RG on current holders of part 50 operating licenses or part 52 combined licenses.

This RG may be applied to applications for operating licenses and combined licenses docketed by the NRC as of the date of issuance of the RG, as well as future applications for operating licenses and combined licenses submitted after the issuance of the RG. Such action does not constitute backfitting as defined in 10 CFR 50.109(a)(1) and is not otherwise inconsistent with the applicable issue finality provision in 10 CFR part 52, inasmuch as such applicants or potential applicants, with exceptions not applicable here, are not within the scope of entities protected by the Backfit Rule or the relevant issue finality provisions in part 52.

Dated at Rockville, Maryland, this 20th day of October 2015.

For the Nuclear Regulatory Commission.

**Thomas H. Boyce,**

*Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.*

[FR Doc. 2015-27110 Filed 10-23-15; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

### Advisory Committee on Reactor Safeguards; Notice of Meeting

In accordance with the purposes of sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting

on November 4–7, 2015, 11545 Rockville Pike, Rockville, Maryland.

**Wednesday, November 4, 2015,  
Conference Room T2–B1, 11545  
Rockville Pike, Rockville, Maryland**

*8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman* (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

*8:35 a.m.–11:00 a.m.: Risk Management Regulatory Framework (RMRF)* (Open)—The Committee will hear presentations by and hold discussions with representatives of the staff regarding the draft SECY paper on possible RMRF implementation.

*1:00 p.m.–4:00 p.m.: Davis-Besse Nuclear Power Station License Renewal* (Open)—The Committee will hear presentations by and hold discussions with representatives of FirstEnergy, and the staff regarding the safety evaluation associated with the Davis-Besse License Renewal Application.

*4:00 p.m.–6:00 p.m.: Preparation of ACRS Reports* (Open)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting.

**Thursday, November 5, 2015,  
Conference Room T2–B1, 11545  
Rockville Pike, Rockville, Maryland**

*8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman* (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

*8:35 a.m.–11:00 a.m.: Fukushima Tier 2/3* (Open)—The Committee will hear presentations by and hold discussions with representatives of the staff regarding Fukushima Tier 2/3 action discussion in support of a SECY paper.

*1:00 p.m.–3:00 p.m.: Status of the Revised Fuel Cycle Oversight Process (RFCOP) Cornerstones* (Open)—The Committee will hear presentations by and hold discussions with representatives of the staff regarding the status of the RFCOP Cornerstones.

*3:00 p.m.–6:00 p.m.: Preparation of ACRS Reports* (Open)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting.

**Friday, November 6, 2015, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland**

*8:30 a.m.–10:00 a.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee* (Open/Closed)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS Meetings, and matters related to the

conduct of ACRS business, including anticipated workload and member assignments. [Note: A portion of this meeting may be closed pursuant to 5 U.S.C. 552b (c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

*10:00 a.m.–10:15 a.m.: Reconciliation of ACRS Comments and Recommendations* (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports and letters.

*1:00 p.m.–6:00 p.m.: Preparation of ACRS Reports* (Open)—The Committee will continue its discussion of proposed ACRS reports on matters discussed during this meeting.

**Saturday, November 7, 2015,  
Conference Room T2–B1, 11545  
Rockville Pike, Rockville, Maryland**

*8:30 a.m.–11:30 a.m.: Preparation of ACRS Reports* (Open)—The Committee will continue its discussion of proposed ACRS reports.

*11:30 a.m.–12:00 p.m.: Miscellaneous* (Open)—The Committee will continue its discussion related to the conduct of Committee activities and specific issues that were not completed during previous meetings.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 1, 2014 (79 FR 59307). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff (Telephone: 301–415–5844, Email: [Quynh.Nguyen@nrc.gov](mailto:Quynh.Nguyen@nrc.gov)), five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

Thirty-five hard copies of each presentation or handout should be provided 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Cognizant ACRS Staff one day before meeting. If an electronic copy cannot be

provided within this timeframe, presenters should provide the Cognizant ACRS Staff with a CD containing each presentation at least 30 minutes before the meeting.

In accordance with subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of the November 6th meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room at [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov), or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> or <http://www.nrc.gov/reading-rm/doc-collections/ACRS/>.

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m. (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated at Rockville, Maryland, this 20th day of October, 2015.

For the Nuclear Regulatory Commission.

**Andrew L. Bates,**

*Advisory Committee Management Officer.*

[FR Doc. 2015–27192 Filed 10–23–15; 8:45 am]

**BILLING CODE 7590–01–P**

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**POSTAL REGULATORY COMMISSION**

[Docket Nos. CP2016–9; Order No. 2767]

**Change in Postal Rates**

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission is noticing a recent Postal Service filing concerning the Postal Service's intention to change rates of general applicability for competitive products. This notice



informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** *Comments are due:* October 29, 2015.

**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:** On October 16, 2015, the Postal Service filed notice with the Commission concerning changes in rates of general applicability for competitive products.<sup>1</sup> The Notice also includes related classification changes. The Postal Service represents that, as required by the Commission's rules, 39 CFR 3015.2(b), the Notice includes an explanation and justification for the changes, the effective date, and a schedule of the changed rates. Notice at 1. The changes are scheduled to become effective January 17, 2016. *Id.*

Attached to the Notice is Governors' Decision No. 15-1, which evaluates the new prices and classification changes in accordance with 39 U.S.C. 3632, 3633, and 39 CFR 3015.2.<sup>2</sup> The Governors' Decision provides an analysis of the competitive products' price and classification changes intended to demonstrate that the changes comply with 39 U.S.C. 3633 and 39 CFR part 3015. Governors' Decision No. 15-1 at 1.

The attachment to Governors' Decision No. 15-1 sets forth the price changes and includes draft Mail Classification Schedule (MCS) language for competitive products of general applicability. Selected highlights of the price and classification changes follow.

**Priority Mail Express.** Priority Mail Express prices increase, on average, by 15.6 percent. The existing structure of Priority Mail Express Retail, Commercial Base, and Commercial Plus

price categories does not change. The proposed prices for Priority Mail Express Retail, Commercial Base, and Commercial Plus increase by 14.4 percent, 17.7 percent, and 48.2 percent respectively. Due to insufficient demand, the Postal Service proposes eliminating the Priority Mail Express Flat Rate Box price category. Governors' Decision No. 15-1 at 2.

**Priority Mail.** Priority Mail prices increase, on average, by 9.8 percent. The existing structure of Priority Mail Retail, Commercial Base, and Commercial Plus price categories does not change. The proposed prices for Priority Mail Retail, Commercial Base, and Commercial Plus increase by 8.6 percent, 9.4 percent, and 13.3 percent respectively. Due to low customer usage, the Postal Service also proposes eliminating Regional Rate Box C and Critical Mail. *Id.* at 2-3.

**Parcel Select.** Non-Lightweight Parcel Select prices increase, on average, by 3.1 percent. The average price for destination entered parcels and non-destination entered parcels increase by 4.9 percent and 1.9 percent respectively. The proposed prices for Lightweight Parcel Select increase by 23.5 percent. The proposed prices for Parcel Select Nonpresort, which the Postal Service rebrands as Parcel Select Ground, increase by 1.9 percent. To simplify product offerings, the Postal Service proposes to eliminate the Parcel Select Origin Network Distribution Center Presort and Network Distribution Center Presort price categories. *Id.* at 3.

**Parcel Return Service.** Parcel Return Service prices increase, on average, by 5.0 percent. The price for parcels picked up at a Return Sectional Center Facility will increase by 5.0 percent as will the price for parcels picked up at a Return Delivery Unit. Due to low customer demand, the Postal Service proposes eliminating the Return Network Distribution Center pricing category. *Id.*

**First-Class Package Service.** First-Class Package Service prices increase, on average, by 12.8 percent. The Postal Service proposes to eliminate the 3-digit, 5-digit, and Area Distribution Center presort levels to simplify the product. Additionally, to streamline the product, the Postal Service proposes consolidating the 14, 15, and 15.999 ounce offerings under the Commercial Plus price category and eliminating the Commercial Plus price category. *Id.* at 3-4.

**Standard Post (Retail Ground).** The proposed prices for Standard Post, which the Postal Service rebrands as Retail Ground, increase by 10.0 percent. *Id.* at 4.

**Domestic Extra Services.** Prices for several Domestic Extra Services are

proposed to increase. The retail counter enrollment fee for Premium Forwarding Service (PFS) increases to \$18.65. The online enrollment fee for PFS increases to \$17.10. The weekly reshipment fee for PFS increases to \$18.65. Prices for Adult Signature service will increase to \$5.70 for the basic service and \$5.95 for the person-specific service. Address Enhancement Service prices increase up to 7.1 percent. Competitive Post Office Box prices increase by, on average, 3.5 percent. The proposed price increase for Package Intercept Service is 3.3 percent. *Id.*

**Global Express Guaranteed and Priority Mail Express International.** Overall, Global Express Guaranteed service prices increase by 7.1 percent. Priority Mail Express International (PMEI) service prices increase by 11.6 percent. Commercial Plus prices will be equivalent to Commercial Base prices and deeper discounting may be available to customers through negotiated service agreements. Prices for PMEI Flat Rate Envelopes will be further separated into additional country groups. Due to low customer usage, the Postal Service proposes eliminating the PMEI Flat Rate Box product. *Id.* at 4-5.

**Priority Mail International.** Overall, Priority Mail International (PMI) prices increase by 10.2 percent. Commercial Plus prices will be equivalent to Commercial Base prices and deeper discounting may be available to customers through negotiated service agreements. Prices for PMI Flat Rate Envelopes and Boxes will be further separated into additional country groups. "Insurance will be offered up to \$200 for merchandise and \$100 for documents in lieu of weight-based indemnity available under current international exchanges." For PMI pieces destined for Canada, a fee will be established for the International Service Center zone chart in order to determine applicable Origin Zone. In accordance with the elimination of Regional Rate Box C from domestic Priority Mail, PMI Regional Rate Box C will no longer be available for PMI Regional Rate Boxes Contracts or PMI Regional Rate Boxes—Non-published Rates Contracts. *Id.* at 5.

**International Priority Airmail and International Surface Air Lift.** The published prices for International Priority Airmail (IPA) and International Surface Air Lift (ISAL) are proposed to increase by 4.2 percent and 6.3 percent respectively. IPA and ISAL M-Bags are proposed to increase by 3.5 percent and 5.3 percent respectively. *Id.*

**Airmail M-Bags.** The published prices for Airmail M-Bags increase by 9.2 percent. *Id.*

<sup>1</sup> Notice of the United States Postal Service of Changes in Rates of General Applicability for Competitive Products Established in Governors' Decision No. 15-1, October 16, 2015 (Notice). Pursuant to 39 U.S.C. 3632(b)(2), the Postal Service is obligated to publish the Governors' Decision and record of proceedings in the **Federal Register** at least 30 days before the effective date of the new rates or classes.

<sup>2</sup> Decision of the Governors of the United States Postal Service on Changes in Rates and Classes of General Applicability for Competitive Products (Governors' Decision No. 15-1), September 17, 2015 (Governors' Decision No. 15-1).



*First-Class Package International Service.* Overall, prices for First-Class Package International Service (FCPIS) increase by 21.6 percent. Commercial Plus prices will be equivalent to Commercial Base prices and deeper discounting may be available to customers through negotiated service agreements. *Id.*

*International Ancillary Services and Special Services.* Overall, International Postal Money Orders prices increase by 5.6 percent. The International Money Order Inquiry Fee increases by 3.5 percent. The International Money Transfer Service prices increase up to 3.7 percent. *Id.* at 6.

Further details of these changes may be found in the attachment to Governors' Decision No. 15-1, which is included as part of the Notice and contains proposed changes to the MCS in legislative format.

The Notice also includes three additional attachments:

- A redacted table showing FY 2016 projected volumes, revenues, attributable costs, contribution, and cost coverage for each product, assuming implementation of the new prices on January 17, 2016.
- A redacted table showing FY 2016 projected volumes, revenues, attributable costs, contribution, and cost coverage for each product, assuming a hypothetical implementation of the new prices on October 1, 2015.

- An application for non-public treatment of the attributable costs, contribution, and cost coverage data in the unredacted version of the annex to Governors' Decision No. 15-1, as well as the supporting materials for the data.

The table referenced above shows that the share of institutional cost generated by competitive products, assuming implementation of new prices on January 17, 2016, is expected to be 15.8 percent.

*Notice.* The Commission establishes Docket No. CP2016-9 to consider the Postal Service's Notice. Interested persons may express views and offer comments on whether the planned changes are consistent with 39 U.S.C. 3632, 3633, 3642, 39 CFR part 3015, and 39 CFR 3020 subparts B and E.

Comments are due no later than October 29, 2015. For specific details of the planned price and classification changes, interested persons are encouraged to review the Notice, which is available on the Commission's Web site, [www.prc.gov](http://www.prc.gov).

Pursuant to 39 U.S.C. 505, Tracy N. Ferguson is appointed to serve as Public Representative to represent the interests of the general public in this docket.

*It is ordered:*

1. The Commission establishes Docket No. CP2016-9 to provide interested persons an opportunity to express views and offer comments on whether the planned changes are consistent with 39 U.S.C. 3632, 3633, 3642, 39 CFR part 3015, and 39 CFR 3020 subparts B and E.

2. Comments are due no later than October 29, 2015.

3. The Commission appoints Tracy N. Ferguson to serve as Public Representative to represent the interests of the general public in this proceeding.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

**Ruth Ann Abrams,**

*Acting Secretary.*

[FR Doc. 2015-27096 Filed 10-23-15; 8:45 am]

**BILLING CODE 7710-FW-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76203; File No. SR-CBOE-2015-088]

### Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Disaster Recovery

October 20, 2015.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on October 8, 2015, Chicago Board Options Exchange, Incorporated ("Exchange" or "CBOE") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to section 19(b)(3)(A)(iii) of the Act<sup>3</sup> and Rule 19b-4(f)(6) thereunder.<sup>4</sup> The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 6.18 relating to disaster recovery. The text of the proposed rule change is

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>4</sup> 17 CFR 240.19b-4(f)(6).

available on the Exchange's Web site (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

The Exchange proposes to amend Rule 6.18 relating to disaster recovery. Specifically, the Exchange proposes to update Rule 6.18 to further describe the Exchange's back-up systems, the circumstances under which they may be used, and the testing that the Exchange may conduct to ensure the availability, functionality and performance of such systems. Additionally, the Exchange proposes certain updates to Rule 6.18 in response to new disaster recovery regulations and business resumption standards recently adopted by the Securities and Exchange Commission ("SEC" or "Commission") as promulgated in Regulation Systems Compliance and Integrity ("Regulation SCI") under the Act.<sup>5</sup>

###### Background

The Exchange adopted Rule 6.18 in 2006 for the limited purpose of providing alternative means of operation in the event of a physical disaster. In particular, Rule 6.18, as originally adopted, was intended to deal with trading floor closures, providing for the operation of a "Disaster Recovery Facility" ("DRF") in the event that a disaster or other unusual circumstance rendered the trading floor inoperable.<sup>6</sup>

<sup>5</sup> See Securities Exchange Act Release No. 73639 (November 19, 2014), 79 FR 72252 (December 5, 2014) (Regulation Systems Compliance and Integrity) (File No. S7-01-13).

<sup>6</sup> See Securities Exchange Act Release No. 54171 (July 19, 2006), 71 FR 42427 (July 26, 2006) (Order Approving Proposed Rule Change and Amendment

Under original Rule 6.18, if the Exchange were forced to halt trading due to a disaster or other physical impairment of its trading floor, the Exchange and its members<sup>7</sup> could operate remotely in a screen-based only environment from the DRF while the trading floor was unavailable. While operating from the DRF, open outcry trading would be suspended.

In 2012, Rule 6.18 was amended in connection with the Exchange's relocation of its primary data center to the East Coast and the consequent conversion of its former primary data center to a back-up data center in Chicago.<sup>8</sup> Specifically, Rule 6.18 was amended to deal with newly possible situations in which the primary data center could continue to operate despite the trading floor being rendered inoperable or in which the back-up data center might be used despite the trading floor being operational. Specifically, as amended, Rule 6.18 provided that in the event that the Exchange were forced to switch operations to the back-up data center, the Exchange's trading floor could still be used and that in the event that the trading floor were inoperable, the Exchange could still operate using a floorless configuration or screen-based only environment on the Exchange's primary data center. References to the DRF and other irrelevant portions of the original rule were eliminated or replaced with references to [sic] Exchange's primary and back-up data centers as appropriate.

In addition to adding greater detail to the Exchange's disaster recovery rules in Rule 6.18, the Exchange proposes to make updates to Rule 6.18 to harmonize its disaster recovery rules with the newly implemented disaster recovery-related regulatory imperatives of Regulation SCI. Regulation SCI supersedes and replaces the SEC's voluntary Automation Review Policy ("ARP"), established by the Commission's two policy statements each titled "Automated Systems of Self-Regulatory Organizations," issued in 1989 and 1991, expanding existing

practices and making them mandatory.<sup>9</sup> As part of Regulation SCI, the Exchange is required to maintain back-up and recovery capabilities with sufficient resiliency and geographical diversity and that are reasonably designed to achieve next business-day resumption of trading and two-hour resumption of critical systems following a wide-scale disruption.<sup>10</sup> The Exchange must also participate in at least annual testing of its business continuity and disaster recovery plans and, to that end, develop and adopt standards to designate which of its TPHs must participate in testing in order to reasonably ensure the maintenance of a fair and orderly market if the Exchange's disaster recovery plan must be activated.<sup>11</sup> Although the Exchange's current Rules provide the Exchange sufficient authority to meet its disaster recovery-related obligations under Regulation SCI, the Exchange believes that certain clarifying updates to the Rules are warranted in light of Regulation SCI.

#### Proposed Rule Changes

The Exchange proposes to make changes to Rule 6.18 to provide additional details regarding the Exchange's back-up trading systems and business continuity and disaster recovery plans activation and testing. As discussed above, the Exchange also seeks to update its disaster recovery rules to ensure consistency with Regulation SCI.

Current Rule 6.18 is divided into five sections, (a) through (e). Rule 6.18(a) authorizes the Exchange to maintain a back-up data center to preserve the Exchange's ability to trade options in the event the Exchange's primary data center becomes inoperable or otherwise unavailable for use. Rule 6.18(a) also authorizes the Exchange to operate in a screen-based only environment using a floorless configuration in the event that the trading floor becomes inoperable. Rule 6.18(b) describes the notice that must be given prior to commencing trading on back-up data center systems. Rule 6.18(c) describes the rules that would be in effect if the Exchange were to switch its trading operations to the back-up data center and the rules that would be suspended if the Exchange were to operate in a screen-based only environment using a floorless configuration in the event that the trading floor becomes inoperable. Rule 6.18(d), prescribes that TPHs are

required to take appropriate actions as instructed by the Exchange to accommodate the Exchange's ability to trade options via the back-up data center. Finally, current Rule 6.18(e) provides that nothing in 6.18 precludes the Exchange from entering into agreements to trade options elsewhere in accordance with Rule 6.16 (Back-up Trading Arrangements) in the event that the Exchange's trading floor is rendered inoperable.

The Exchange proposes to make rule changes to Rule 6.18 that would leave the current rule largely intact, but reorganized with detail added to each section of the current rule. Under proposed Rule 6.18(a) (General), rather than explaining the Exchange's back-up data center and alternative disaster-related trading configurations in the introductory section, the Exchange would adopt a general statement regarding the purpose of its disaster recovery rules, providing that the Exchange maintains business continuity and disaster recovery plans that may be effected in the interests of the continued operation of fair and orderly markets in the event of a systems failure, disaster, or other unusual circumstances that might threaten the ability to conduct business on the Exchange. The content of current Rule 6.18(a) would be moved from the general section of Rule 6.18(a) to proposed Rule 6.18(b) regarding the Exchange's back-up data center.

Proposed Rule 6.18(b) (Back-up Data Center), would mirror current Rule 6.18(a), but would include a definitive statement that the Exchange maintains a back-up data center in order to preserve the Exchange's ability to conduct business in the event the Exchange's primary data center becomes inoperable or otherwise unavailable for use, rather than providing that the Exchange may maintain such back-up facilities. The Exchange also proposes to change the text of current Rule 6.18(a) in proposed Rule 6.18(b) to provide that the Exchange maintains a back-up data center in order to preserve the Exchange's ability to conduct business in the event the Exchange's primary data center becomes inoperable or otherwise unavailable for use, rather than to preserve only the Exchange's ability to trade options. This proposed rule change reflects the fact that the Exchange is engaged in business activities other than just the trading of options, including, but not limited to providing market data services and conducting regulatory functions.

Whereas the Exchange's current rules provide that the Exchange may determine to switch operations from the primary data center to the back-up data

No. 1 Thereto Regarding a Disaster Recovery Facility) (SR-CBOE-2006-001[sic]).

<sup>7</sup> Prior to its demutualization in 2010, the Exchange was a member-owned organization. See Securities Exchange Act Release No. 62382 (June 25, 2010), 75 FR 38164 (July 1, 2010) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Conforming Changes in Connection With Demutualization) (SR-CBOE-2010-058).

<sup>8</sup> See Securities Exchange Act Release No. 68301 (November 27, 2012), 77 FR 71650 (December 3, 2012) (Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change To Amend CBOE Rule 6.18 Concerning the Exchange's Disaster Recovery Facility) (SR-CBOE-2012-111).

<sup>9</sup> See Securities Exchange Act Release No. 73639 (November 19, 2014), 79 FR at 72252 (December 5, 2014) (Regulation Systems Compliance and Integrity) (File No. S7-01-13).

<sup>10</sup> 17 CFR 242.1001(a)(2)(v).

<sup>11</sup> *Id.* at 242.1004.

center due to a disaster or other unusual circumstances, proposed Rule 6.18(b) would add the scenario of a significant systems failure to the list of causes that may trigger an operational switch to the Exchange's back-up data center. The proposed addition of significant systems failures to the list of scenarios that may trigger an operational switch to the Exchange's back-up data center is intended to more acutely reflect the realities of electronic trading environments and contemporary threats posed to the operation of fair and orderly markets. The statements in current Rule 6.18(a) regarding contingent alternative plans in the event that the Exchange's trading floor becomes inoperable would be removed from the section and relocated to proposed Rule 6.18(c) (Loss of Trading Floor), which would be dedicated to the details of the Exchange's authority in the event that the Exchange trading floor becomes inoperable. In addition to the reformulation of the description of the Exchange's back-up data center in proposed Rule 6.18(b), proposed Rule 6.18(b) would also contain subsections setting forth the notice, applicable rules, and Trading Permit Holder ("TPH") preparations provisions currently contained in Rules 6.18(b) through (d).

Proposed Rule 6.18(b)(i) (Back-up Data Center Functionality), would make clear the functional and performance standards that the back-up data center must be reasonably designed to achieve. Specifically, proposed Rule 6.18(b)(i) would provide that the Exchange maintains a back-up data center that the Exchange has determined is reasonably designed to achieve prompt resumption of systems in [sic] manner consistent with the Exchange's obligations under Regulation SCI.<sup>12</sup> Proposed Rule 6.18(b)(i) would also provide that nothing in the provisions of proposed Rule 6.18(b) shall be interpreted to require the Exchange to develop or maintain a back-up data center designed to fully replicate the capacity, latency, and other features of the primary data

center. This statement attempts to make clear that in order to preserve the Exchange's ability to conduct business in the event the Exchange's primary data center becomes inoperable or otherwise unavailable for use, the Exchange must maintain a back-up data center that is reasonably designed to achieve resumption of systems in a manner consistent with Regulation SCI during a significant systems failure, disaster or other unusual circumstances, rather than replicate the Exchange's primary data center systems. The Exchange believes that the standards set forth in proposed Rule 6.18(b)(i) are reasonable to help ensure the maintenance of fair and orderly markets in the event of a significant systems failure, disaster or other unusual circumstances and are consistent with provisions in the release language of Regulation SCI.<sup>13</sup>

Proposed Rule 6.18(b)(ii) (Notice), would be the same as current Rule 6.18(b) and provide that prior to commencing trading on the back-up data center, the Exchange shall announce publicly the classes that will be available for trading. Proposed Rule 6.18(b)(iii) (Applicable Rules) would be the same as current Rule 6.18(c) and provide that the same rules that apply to trading using primary data center systems would be applicable to trading on back-up data center systems. The applicable rule exceptions with respect to the suspension of open outcry trading on the floor, however, would be removed from proposed Rule 6.18(b)(iii) and relocated to proposed Rule 6.18(c) (Loss of Trading Floor). Accordingly, proposed Rule 6.18(b)(iii) would provide that in the event the primary data center becomes inoperable, trading will continue using the back-up data center and all trading rules will remain in effect. Consistent with current Rule 6.18(c), the proposed rule would also contain the provisions that only conduct permissible pursuant to trading rules that are in force shall be allowed via the back-up data center and that all non-trading rules of the Exchange shall continue to apply.

Proposed Rule 6.18(b)(iv) (Trading Permit Holder Participation) regarding testing of the Exchange's back-up data center would contain provisions similar to current Rule 6.18(d) (Trading Permit Holder Preparations), but add subparagraphs to more clearly articulate the Exchange's authority to conduct testing of its back-up data center

systems. Thus, similar to current Rule 6.18(d), proposed Rule 6.18(b)(iv) would provide that TPHs are required to take appropriate actions as instructed by the Exchange to accommodate the Exchange's ability to trade options via the back-up data center. Similar to the proposed changes to the text of current Rule 6.18(a) with respect to the purpose for which the Exchange maintains a back-up data center, for the reasons discussed above, the Exchange also proposes changing the rule text in proposed Rule 6.18(b)(iv) to provide that TPHs are required to take appropriate actions as instructed by the Exchange to accommodate the Exchange's ability to conduct business via the back-up data center, rather than solely to accommodate the Exchange's ability to conduct business [sic]. Under the proposed rule change, the title of current Rule 6.18(d) (Trading Permit Holder Preparations) would also be changed in proposed Rule 6.18(b)(iv) (Trading Permit Holder Participation) to better describe the purpose of the rule provisions.

Subsections (A) through (C) of proposed Rule 6.18(b)(iv) are designed to harmonize the Exchange's back-up data center testing rules with certain provisions of Regulation SCI. Under proposed Rule 6.18(b)(iv)(A) (Designated BCP/DR Participants), the Exchange shall designate those Trading Permit Holders that the Exchange determines are, as a whole, necessary for the maintenance of fair and orderly markets in the event of the activation of the Exchange's business continuity and disaster recovery plans ("Designated BCP/DR Participants"). Under proposed Rule 6.18(b)(iv)(A)(1), Designated BCP/DR Participants will be identified based on criteria determined by the Exchange and announced via Regulatory Circular, which may include whether the Trading Permit Holder ("TPH") is an appointed Designated Primary Market-Maker ("DPM"), Lead Market-Maker ("LMM") or Market-Maker in a class and the quality of markets provided by the DPM, LMM, or Market-Maker,<sup>14</sup> the amount of volume transacted by the market participant in a class or on the Exchange in general, operational capacity, trading experience, and historical contribution to fair and orderly markets on the Exchange. Under proposed Rule 6.18(b)(iv)(A)(2), Designated BCP/DR Participants shall include, at a minimum, all Market-Makers in option

<sup>12</sup> Among other things, Regulation SCI requires that the Exchange "establish, maintain, and enforce written policies and procedures reasonably designed to ensure that its SCI systems . . . have levels of capacity, integrity, resiliency, availability, and security, adequate to maintain . . . [sic] [the Exchange's] operational capability and promote the maintenance of fair and orderly markets." See 17 CFR 242.1001(a)(1). With respect to business continuity and disaster recovery plans, such standards mean that, at a minimum, the Exchange shall maintain "backup and recovery capabilities sufficiently resilient and geographically diverse [sic] that they [sic] are reasonably designed to achieve next business day resumption of trading and two-hour resumption of critical SCI systems following a wide-scale disruption." See *id.* at § 242.1001(a)(2)(v).

<sup>13</sup> See Securities Exchange Act Release No. 73639 (November 19, 2014), 79 FR at 72353 (December 5, 2014) (Regulation Systems Compliance and Integrity) (File No. S7-01-13).

<sup>14</sup> Among other things, quality of markets provided refers to the average size quoted in a class, percentage quoting on NBBO, how many series are quoted in a class, and how many calendar months out from present day a participant normally quotes.

classes exclusively listed on the Exchange that stream quotes in such classes and all DPMs in multiply listed option classes. Although under the proposed rule, Designated BCP/DR Participants would definitively include all Market-Makers in option classes exclusively listed on the Exchange that stream quotes in such classes and all DPMs in multiply listed option classes, the proposed rule would leave open the possibility that other market participants might be designated by the Exchange as Designated BCP/DR Participants based on certain of the criteria listed in proposed Rule 6.18(b)(iv)(A)(1) and announced via Regulatory Circular. Any changes to the standards by which a market participant might be determined to be a Designated BCP/DR Participant would be applied prospectively with reasonable advance notice as announced via Regulatory Circular. The Exchange would first announce the criteria by which market participants would be determined to be Designated BCP/DR Participants by November 1, 2015.

The Exchange has attempted to model the provisions of proposed Rule 6.18(b)(iv)(A) based on provisions of Regulation SCI, which require the Exchange to establish standards for the designation of those members or participants that the Exchange reasonably determines are, taken as a whole, the minimum number of members or participants necessary for the maintenance of fair and orderly markets in the event of the activation of its business continuity and disaster recovery plans.<sup>15</sup> Also consistent with Regulation SCI, proposed Rule 6.18(b)(iv)(B) (Fair and Orderly Market Conditions) would make clear that nothing in proposed Rule 6.18(b) would require the Exchange to assume that average levels of liquidity, depth, or other characteristics of a usual trading session must be present in order to achieve a fair and orderly market in the event of the activation of the Exchange's business continuity and disaster recovery plans.<sup>16</sup>

Proposed Rule 6.18(b)(iv)(C) (Business Continuity and Disaster Recovery Plans Testing), would provide that The [sic] Exchange shall require Designated BCP/DR Participants and may require other market participants to participate in scheduled business continuity and disaster recovery plans tests in the manner and frequency prescribed by the

Exchange. Proposed Rule 6.18(b)(iv)(C) would set forth the Exchange's authority to conduct testing of business continuity and disaster recovery plans and obtain assistance from Designated BCP/DR Participants and other market participants in conducting such tests. The Exchange notes that the provisions of proposed Rule 6.18(b)(iv)(C) are consistent with the Exchange's current rules<sup>17</sup> as well as provisions of Regulation SCI pertaining to business continuity and disaster recovery plan testing.<sup>18</sup> Proposed Rule 6.18(b)(iv)(C)(1) (Documentation and Reports), would provide that the Exchange may require Designated BCP/DR Participants and/or other market participants to provide documentation and reports regarding tests conducted pursuant to Rule 6.18, including related data and information, as may be requested by the Exchange, and in the manner and frequency prescribed by the Exchange. Proposed Rule 6.18(b)(iv)(C)(2) (Notice), would provide that the Exchange will provide reasonable prior notice of scheduled business continuity and disaster recovery plans tests to Trading Permit Holders, which notice shall describe the general nature of the test(s) and identify the Trading Permit Holders required to participate and shall be announced via Regulatory Circular.

Proposed Rule 6.18(c) (Loss of Trading Floor), would be substantially similar to provisions in current Rule 6.18(a) (General), regarding loss of the trading floor, which would be removed from proposed Rule 6.18(b) (Back-up Data Center) and more appropriately placed in a separate section regarding the Exchange's trading floor facilities. Under proposed Rule 6.18(c), if the Exchange trading floor were to become inoperable, the Exchange would have the authority to continue to operate in a screen-based only environment using a floorless configuration of the Hybrid Trading System located in the primary data center that is operational while the trading floor is inoperable. The Exchange would operate using this configuration only until the Exchange's trading floor facility is operational and open outcry trading would not be available in the event the trading floor becomes inoperable, except in accordance with Rule 6.16 (Back-up Trading Arrangements), as applicable.

Proposed Rule 6.18(c)(i) (Applicable Rules), would mirror current Rule 6.18(c) (Applicable Rules), except that

the current rule would be updated in proposed Rule 6.18(c)(i) to include additional rules pertaining to open outcry trading, including, but not limited to Rule 6.12A (Public Automated Routing System (PAR)) and Rule 7.12 (PAR Official). Thus, under proposed Rule 6.18(c)(i), in the event that the trading floor becomes inoperable, trading would be conducted pursuant to all applicable Hybrid System rules, except that open-outcry rules would not be in force. In these circumstances, a non-exclusive list of open outcry trading rules that would not apply would include either all, or some portion of, Rules 6.2, 6.2A, 6.8, 6.8B, 6.9, 6.12; 6.12A, 6.13A, 6.20, 6.22, 6.23, 6.45, 6.47, 6.54, 6.74, 7.12, 8.15, and 8.17.<sup>19</sup> Proposed Rule 6.18(c)(ii) (Other Back-up Trading Arrangements), would be similar to current Rule 6.18(e), making clear that proposed Rule 6.18 would not preclude the Exchange from conducting business on the floor of another exchange pursuant to Rule 6.16 (Back-up Trading Arrangements), in the event the trading floor is rendered inoperable.

## 2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of section 6(b) of the Act<sup>20</sup> and Regulation SCI.<sup>21</sup> Specifically, the Exchange believes the proposed rule change is consistent with the section 6(b)(5)<sup>22</sup> requirements that the rules of an exchange be 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

<sup>19</sup> In an effort to shorten and simply [sic] the Exchange's disaster recovery rule, the Exchange proposes to eliminate redundant parenthetical information referencing the titles of each of the rules cited in Rule 6.18. The rules and respective titles of the rules cited in proposed Rule 6.18(c)(i) include the following: 6.2 (Trading Rotations); 6.2A (Rapid Opening System); 6.8 (RAES Operations); 6.8B (Automatic ORS Order Execution Against Booked Orders); 6.9 (Solicited Transactions); 6.12 (CBOE Hybrid Order Handling System); 6.12A (Public Automated Routing System (PAR)); 6.13A (Simple Auction Liaison (SAL)); 6.20 (Admission to and Conduct on the Trading Floor; Trading Permit Holder Education); 6.22 (Trading by Trading Permit Holders on the Floor); 6.23 (Trading Permit Holder Wires from Floor [sic]); 6.45 (Priority of Bids and Offers—Allocation of Trades); 6.47 (Priority on Split-Price Transactions Occurring in Open Outcry); 6.54 (Accommodation Liquidations (Cabinet Trades)); 6.74 (Crossing Orders); 7.12 (PAR Official); 8.15 (Lead Market-Makers and Supplemental Market-Makers in Hybrid 3.0 Classes); and 8.17 (Stopping of Option Orders).

<sup>20</sup> 15 U.S.C. 78f(b).

<sup>21</sup> See 17 CFR 242.1001(a) and 1004.

<sup>22</sup> 15 U.S.C. 78f(b)(5).

<sup>15</sup> See 17 CFR 242.1004(a)–(b).

<sup>16</sup> See Securities Exchange Act Release No. 73639 (November 19, 2014), 79 FR at 72353 (December 5, 2014) (Regulation Systems Compliance and Integrity) (File No. S7–01–13).

<sup>17</sup> See Rules 6.23A (Trading Permit Holder Connectivity); 6.18(d) (Trading Permit Holder Preparations).

<sup>18</sup> See 17 CFR 242.1004(a)–(b).

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. Additionally, the Exchange believes the proposed rule change is consistent with the section 6(b)(5)<sup>23</sup> requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposed rule change is designed to promote the Exchange's ability to ensure the continued operation of a fair and orderly market in the event of a systems failure, disaster, or other unusual circumstances that might threaten the ability to conduct business on the Exchange. The Exchange recognizes that switching operations to the back-up data center may occur in times of uncertainty or great volatility in the markets. It is at these times that the investors may have the greatest need for viable, trustworthy marketplaces. The proposed rule changes seek to ensure that such a marketplace will exist when most needed. Accordingly, the Exchange believes that the proposed rule protects investors in the most fundamental sense by helping to ensure that a fair and orderly market will exist at a time when such a market may be most needed.

The Exchange also believes that the proposed rule change promotes just and equitable principles of trade by adding detail and clarity to the Rules. The proposed rule change seeks to provide additional clarity to the Exchange's disaster recovery rules, putting all market participants on notice as to how the Exchange will function in case of significant systems disruption or other disaster situation. The Exchange is continuously updating the Rules to provide additional detail, clarity, and transparency regarding its operations and trading systems and regulatory authority. The Exchange believes that the adoption of detailed, clear, and transparent rules reduces burdens on competition and promotes just and equitable principles of trade. The Exchange also believes that adding greater detail to the Rules regarding the Exchange's ability to ensure the continuous operation of the market and preserve the ability to conduct business on the Exchange will increase confidence in the markets and encourage wider participation in the markets and greater investment. Finally, the Exchange notes that proposed Rule

6.18 is designed to harmonize the Exchange's disaster recovery rules with Regulation SCI under the Act.

#### *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. Rather, the proposed rule change will help ensure that competitive markets remain operative in the event of a systems failure or other disaster event. The Exchange notes that the proposed rule change is designed to clarify the Exchange's authority to require market participants to participate in, and provide necessary liquidity to ensure fair and orderly markets. The Exchange further notes that the proposed rule change is designed to ensure competitive markets in that it is designed around the mandates of Regulation SCI, which each of the national securities exchanges is required to satisfy.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange neither solicited nor received written comments on the proposed rule change.

### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act<sup>24</sup> and Rule 19b-4(f)(6) thereunder.<sup>25</sup>

A proposed rule change filed under Rule 19b-4(f)(6)<sup>26</sup> normally does not become operative for 30 days after the date of filing. However, pursuant to

<sup>24</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>25</sup> 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission deems this requirement to have been met.

<sup>26</sup> 17 CFR 240.19b-4(f)(6).

Rule 19b-4(f)(6)(iii)<sup>27</sup> the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. According to the Exchange, the proposed rule change does not present any novel or controversial issues. Rather, the Exchange is merely reorganizing its existing rule, updating cross-references to incorporate previously adopted rules, or adding provisions that are consistent with or required by Regulation SCI. In addition, the Exchange has represented that much of the proposed rule change is already permitted under the Exchange's existing rule. Accordingly, 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 Exchange to incorporate changes required under Regulation SCI, such as establishing standards for designating BCP/DR Participants, prior to the November 3, 2015 compliance date. Therefore, the Commission designates the proposed rule change to be operative upon filing.<sup>28</sup>

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](mailto:rule-comments@sec.gov). Please include File Number SR-CBOE-2015-088 on the subject line.

#### *Paper Comments*

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities

<sup>27</sup> 17 CFR 240.19b-4(f)(6)(iii).

<sup>28</sup> For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>23</sup> *Id.*

and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-CBOE-2015-088. 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-CBOE-2015-088, and should be submitted on or before November 16, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>29</sup>

**Brent J. Fields,**  
Secretary.

[FR Doc. 2015-27086 Filed 10-23-15; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76200; File No. SR-EDGX-2015-48]

### Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 19.3 To Allow the Listing of Certain Options Based on International Indexes

October 20, 2015.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the

“Act”),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on October 9, 2015, EDGX Exchange, Inc. (the “Exchange” or “EDGX”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a “non-controversial” proposed rule change pursuant to section 19(b)(3)(A) of the Act<sup>3</sup> and Rule 19b-4(f)(6)(iii) thereunder,<sup>4</sup> which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to allow the listing of options overlying portfolio depositary receipts and index fund shares (collectively, “ETFs”) that are listed pursuant to generic listing standards on equities exchanges for series of ETFs based on international or global indexes under which a comprehensive surveillance sharing agreement is not required.

The text of the proposed rule change is available at the Exchange's Web site at [www.batstrading.com](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 is proposing to amend Rule 19.3(i) to allow the Exchange's options platform (“EDGX Options”) to

list options overlying ETFs that are listed pursuant to generic listing standards on equities exchanges for series of ETFs based on international or global indexes under which a comprehensive surveillance sharing agreement (“CSSA”) is not required.<sup>5</sup> This proposal will enable the Exchange to list and trade options on ETFs without a CSSA provided that the ETF is listed on an equities exchange pursuant to the generic listing standards that do not require a CSSA pursuant to Rule 19b-4(e) of the Exchange Act.<sup>6</sup> Rule 19b-4(e) provides that the listing and trading of a new derivative securities product by a self-regulatory organization (“SRO”) shall not be deemed a proposed rule change, pursuant to paragraph (c)(1) of Rule 19b-4, if the Commission has approved, pursuant to section 19(b) of the Exchange Act, the SRO's trading rules, procedures, and listing standards for the product class that would include the new derivatives securities product and the SRO has a surveillance program for the product class.<sup>7</sup> In other words, the proposal will amend the listing standards to allow the Exchange to list and trade options on ETFs based on international or global indexes to a similar degree that they are allowed to be listed on several equities exchanges.<sup>8</sup>

Currently, EDGX Options rules allow for the listing and trading of options on Fund Shares. Rule 19.3(i)(1)–(3) provide the listings standards for options on Fund Shares with non-U.S. component stocks, such as Fund Shares based on international or global indexes. Rule 19.3(i)(1) requires that any non-U.S. component stocks of an index or portfolio of stocks on which the Fund Shares are based that are not subject to a CSSA do not in the aggregate represent more than 50% of the weight of the index or portfolio. Rule 19.3(i)(2) requires stocks for which the primary market is in any one country that is not

<sup>5</sup> See, e.g., EDGX Rule 14.2(b)(3); BATS Exchange Rule 14.11(b)(3)(A)(ii); NYSE MKT Rule 1000 Commentary .03(a)(B); NYSE Arca Equities Rule 5.2(j)(3) Commentary .01 (a)(B); and NASDAQ Rule 5705(a)(3)(A)(ii).

<sup>6</sup> 17 CFR 240.19b-4(e).

<sup>7</sup> When relying on Rule 19b-4(e), the SRO must submit Form 19b-4(e) to the Commission within five business days after the SRO begins trading the new derivative securities products. See Exchange Act Release No. 40761 (December 8, 1998), 63 FR 70952 (December 22, 1998).

<sup>8</sup> See EDGX Rule 14.2(b)(3); BATS Rules 14.11(b)(3)(A)(ii); NYSE MKT Rule 1000 Commentary .03(a)(B); NYSE Arca Equities Rule 5.2(j)(3) Commentary .01 (a)(B); and NASDAQ Rule 5705(a)(3)(A)(ii). See also Securities Exchange Act Release Nos. 54739 (November 9, 2006), 71 FR 66993 (SR-Amex-2006-78); 55269 (February 9, 2007), 72 FR 7490 (February 15, 2007) (SR-NASDAQ-2006-050); 55621 (April 12, 2007), 72 FR 19571 (April 18, 2007) (SR-NYSEArca-2006-86)

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>4</sup> 17 CFR 240.19b-4(f)(6)(iii).

<sup>29</sup> 17 CFR 200.30-3(a)(12).

subject to a CSSA do not represent 20% or more of the weight of the index. Rule 19.3(i)(3) requires that stocks for which the primary market is in any two countries that are not subject to a CSSA do not represent 33% or more of the weight of the index.

The Exchange notes that the Commission has previously approved generic listing standards pursuant to Rule 19b-4(e) of the Exchange Act for ETFs based on indexes that consist of stocks listed on U.S. exchanges.<sup>9</sup> In general, the criteria for the underlying component stocks in the international and global indexes are similar to those for the domestic indexes, but with modifications as appropriate for the issues and risks associated with non-U.S. stocks. In addition, the Commission has previously approved the listing and trading of ETFs based on international indexes—those based on non-U.S. component stocks—as well as global indexes—those based on non-U.S. and U.S. component stocks.<sup>10</sup>

In approving ETFs for equities exchange trading, the Commission thoroughly considered the structure of the ETFs, their usefulness to investors and to the markets, and SRO rules that govern their trading. The Exchange believes that allowing the listing of options overlying ETFs that are listed pursuant to the generic listing standards on equities exchanges for ETFs based on international and global indexes and applying Rule 19b-4(e) should fulfill the intended objective of that Rule by allowing options on those ETFs that have satisfied the generic listing standards to commence trading, without the need for the public comment period and Commission approval. The proposed rule has the potential to reduce the time frame for bringing options on ETFs to market, thereby reducing the burdens on issuers and other market participants. The failure of a particular ETF to comply with the generic listing standards under Rule 19b-4(e) would not, however, preclude the Exchange from submitting a separate filing pursuant to section 19(b)(2),<sup>11</sup> requesting Commission approval to list and trade options on a particular ETF. Options on ETFs listed pursuant to these generic standards for international

and global indexes would be traded, in all other respects, under the Exchange's existing trading rules and procedures that apply to options on ETFs and would be covered under the Exchange's surveillance program for options on ETFs.

Pursuant to the proposed rule, the Exchange may list and trade options on an ETF without a CSSA provided that the ETF is listed pursuant to generic listing standards for series of ETFs based on international or global indexes under which a comprehensive surveillance agreement is not required. The Exchange believes that these generic listing standards are intended to ensure that stocks with substantial market capitalization and trading volume account for a substantial portion of the weight of an index or portfolio.

The Exchange believes that this proposed listing standard for options on ETFs is reasonable for international and global indexes, and, when applied in conjunction with the other listing requirements,<sup>12</sup> will result in options overlying ETFs that are sufficiently broad-based in scope and not readily susceptible to manipulation. The Exchange also believes that allowing the Exchange to list options overlying ETFs that are listed on equities exchanges pursuant to generic standards for series of portfolio depository receipts or index fund shares<sup>13</sup> based on international or global indexes under which a CSSA is not required, will result in options overlying ETFs that are adequately diversified in weighting for any single security or small group of securities to significantly reduce concerns that trading in options overlying ETFs based on international or global indexes could become a surrogate for trading in unregistered securities.

The Exchange believes that ETFs based on international and global indexes that have been listed pursuant to the generic standards are sufficiently broad-based enough as to make options overlying such ETFs not susceptible to manipulation. The Exchange believes that the threat of manipulation is sufficiently mitigated for underlying ETFs that have been listed on equities exchanges pursuant to

generic listing standards for series of portfolio depository receipts or index fund shares based on international or global indexes under which a comprehensive surveillance agreement is not required and for the overlying options, that the Exchange does not see the need for CSSA to be in place before listing and trading options on such ETFs. The Exchange notes that its proposal does not replace the need for a CSSA as provided in the current rule. The provisions of the current rule, including the need for a CSSA, remain materially unchanged in the proposed rule and will continue to apply to options on ETFs that are not listed on an equities exchange pursuant to generic listing standards for series of portfolio depository receipts or index fund shares based on international or global indexes under which a comprehensive surveillance agreement is not required. Instead, the proposed rule adds an additional listing mechanism for certain qualifying options on ETFs to be listed on the Exchange.

Finally, the Exchange is also proposing to make several non-substantive changes to the rule text in order to make it easier to read and understand. Specifically, the Exchange is proposing to move paragraph (4) to become paragraph (1), to renumber each of paragraphs (1), (2), (3), (5), and (6) to (B), (C), (D), (E), and (F), respectively, and to make clear that each of the proposed newly numbered paragraphs (B), (C), (D), (E), and (F) apply to the series of Fund Shares that do not meet the criteria proposed in proposed new paragraph (A).

## 2. Statutory Basis

The Exchange believes that its proposal 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(b) of the Act.<sup>14</sup> In particular, the proposal is consistent with section 6(b)(5) of the Act<sup>15</sup> because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. In particular, the proposed rules have the potential to

<sup>9</sup> See Commentary .03 to Amex Rule 1000 and Commentary .02 to Amex Rule 1000A. See also Securities Exchange Act Release No. 42787 (May 15, 2000), 65 FR 33598 (May 24, 2000).

<sup>10</sup> See, e.g., Securities Exchange Act Release Nos. 50189 (August 12, 2004), 69 FR 51723 (August 20, 2004) (approving the listing and trading of certain Vanguard International Equity Index Funds); 44700 (August 14, 2001), 66 FR 43927 (August 21, 2001) (approving the listing and trading of series of the iShares Trust based on certain S&P global indexes).

<sup>11</sup> 15 U.S.C. 78s(b)(2).

<sup>12</sup> All of the other listing criteria under the Exchange's rules will continue to apply to any options listed pursuant to the proposed rule change.

<sup>13</sup> The Exchange notes that the proposed rule text differs slightly from that of other exchanges in order to make clear that the rule applies to ETFs that have been listed on equities exchanges pursuant to generic listing standards for series of "portfolio depository receipts or index fund shares" rather than "portfolio depository receipts and index fund shares." Such difference does not represent a substantive difference from the rules of other Exchanges. See *infra* note 16.

<sup>14</sup> 15 U.S.C. 78f(b).

<sup>15</sup> 15 U.S.C. 78f(b)(5).



reduce the time frame for bringing options on ETFs to market, thereby reducing the burdens on issuers and other market participants. The Exchange also believes that enabling the listing and trading of options on ETFs pursuant to this new listing standard will benefit investors by providing them with valuable risk management tools. The Exchange notes that its proposal does not replace the need for a CSSA as provided in the current rule. The provisions of the current rule, including the need for a comprehensive surveillance sharing agreement, remain materially unchanged in the proposed rule and will continue to apply to options on ETFs that are not listed on an equities exchange pursuant to generic listing standards for series of portfolio depositary receipts or index fund shares based on international or global indexes under which a comprehensive surveillance agreement is not required. Instead, the proposed rule adds an additional listing mechanism for certain qualifying options on ETFs to be listed on the Exchange in a manner that is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange also believes that the proposed non-substantive organizational changes are reasonable, fair, and equitable because they are designed to make the rule easier to comprehend. As noted above, the proposed non-substantive changes do not change the need for a CSSA as provided in the current rule. The provisions of the current rule, including the need for a CSSA, remain materially unchanged in the proposed rule and will continue to apply to options on ETFs that are not listed on an equities exchange pursuant to generic listing standards for series of portfolio depositary receipts or index fund shares based on international or global indexes under which a comprehensive surveillance agreement is not required. These non-substantive changes to the rules are intended to make the rules clearer and less confusing for participants and investors and to eliminate potential confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market

system, and, in general, protecting investors and the public interest.

#### *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. To the contrary, the proposed rule change is a competitive change that is substantially similar to recent rule changes by other options exchanges, such as MIAX Options Exchange ("MIAX"), NASDAQ OMX PHLX, LLC ("Phlx"), and International Stock Exchange LLC ("ISE").<sup>16</sup> The Exchange notes that the Exchange's affiliate, BATS Exchange, Inc. ("BATS") also filed a similar rule change earlier this year.<sup>17</sup> Furthermore, the Exchange believes this proposed rule change will benefit investors by providing additional methods to trade options on ETFs, and by providing them with valuable risk management tools. Specifically, the Exchange believes that market participants on the Exchange would benefit from the introduction and availability of options on ETFs in a manner that is similar to equities exchanges and will provide investors with a venue on which to trade options on these products. For all the reasons stated above, the Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, and believes the proposed change will enhance competition.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange has neither solicited nor received written comments on the proposed rule change.

### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has

<sup>16</sup> See, e.g., Securities Exchange Act Release Nos. 74509 (March 13, 2015), 80 FR 14425 (March 19, 2015) (SR-MIAX-2015-04); 74553 (March 20, 2015), 80 FR 16072 (March 26, 2015) (SR-Phlx-2015-27); and 74832 (April 29, 2015), 80 FR 25738 (May 5, 2015) (SR-ISE-2015-16).

<sup>17</sup> See Securities Exchange Act Release No. 75166 (June 12, 2015), 80 FR 34946 (June 18, 2015) (SR-BATS-2015-43).

become effective pursuant to section 19(b)(3)(A)(iii) of the Act<sup>18</sup> and subparagraph (f)(6) of Rule 19b-4 thereunder.<sup>19</sup>

A proposed rule change filed under Rule 19b-4(f)(6) normally does not become operative prior to 30 days after the date of filing,<sup>20</sup> Rule 19b-4(f)(6)(iii), however, permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest.<sup>21</sup> The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has stated that waiver of the operative delay will permit the Exchange to list and trade certain ETF options on the same basis as other options markets.<sup>22</sup> The Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.<sup>23</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### *Electronic Comments*

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or

<sup>18</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>19</sup> 17 CFR 240.19b-4(f)(6). As required under Rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

<sup>20</sup> 17 CFR 240.19b-4(f)(6)(iii).

<sup>21</sup> *Id.*

<sup>22</sup> See *supra* notes 16 and 17.

<sup>23</sup> For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).



• Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-EDGX-2015-48 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-EDGX-2015-48. 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-EDGX-2015-48, and should be submitted on or before November 16, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>24</sup>

**Brent J. Fields,**  
Secretary.

[FR Doc. 2015-27071 Filed 10-23-15; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76202; File No. SR-NYSEArca-2015-77]

### 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, To List and Trade Shares of the First Trust Heitman Global Prime Real Estate ETF Under NYSE Arca Equities Rule 8.600

October 20, 2015.

#### I. Introduction

On August 28, 2015, NYSE Arca, Inc. ("Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to list and trade shares ("Shares") of the First Trust Heitman Global Prime Real Estate ETF (the "Fund,") under NYSE Arca Equities Rule 8.600. The proposed rule change was published for comment in the *Federal Register* on September 17, 2015.<sup>3</sup> On October 1, 2015, the Exchange filed Amendment No. 1 to the proposed rule change.<sup>4</sup> The Commission received no comments on the proposed rule change. The Commission is publishing this notice to solicit comments on Amendment No. 1 from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

#### II. The Exchange's Description of the Proposed Rule Change<sup>5</sup>

The Exchange proposes to list and trade the Shares under NYSE Arca

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 75901 (September 11, 2015), 80 FR 55892 ("Notice").

<sup>4</sup> In Amendment No. 1, the Exchange: (1) identified the investment objective of the Fund; (2) clarified the scope of the Fund's permitted investments; (3) modified its description of the Fund's Share redemption process; (4) supplemented its description of the availability of price information for the Shares and the underlying assets; (5) identified another entity as the administrator, custodian, and transfer agent for the Fund; and (6) made other technical changes. Amendment No. 1 is available at: <http://www.sec.gov/rules/sro/nysearca/2015/34-75901-amendment1.pdf>.

<sup>5</sup> The Commission notes that additional information regarding the Trust, the Fund, its investments, and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, calculation of net asset value ("NAV"), distributions, and taxes, among other things, can be

found in the Notice and the Registration Statement, as applicable. See Notice, *supra* note 3, and Registration Statement, *infra* note 6.

<sup>6</sup> The Exchange states that the Trust is registered under the 1940 Act. According to the Exchange, on August 27, 2014, the Trust filed an amendment to the Trust's registration statement on Form N-1A under the Securities Act of 1933 (the "1933 Act") (15 U.S.C. 77a), and under the 1940 Act relating to the Fund (File Nos. 333-174332 and 811-22559) (the "Registration Statement"). The Exchange states that the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. See Investment Company Act Release No. 28468 (October 27, 2008) (File No. 812-13477).

<sup>7</sup> The term "under normal market conditions" includes, but is not limited to, the absence of extreme volatility or trading halts in the equity markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

<sup>8</sup> The Fund's investments in Real Estate Securities and certain non-U.S. companies (as referred to below under "Non-Principal Investments") may be in the form of Depositary Receipts, which include American Depositary Receipts, Global Depositary Receipts, and European Depositary Receipts. All Depositary Receipts in which the Fund invests will be traded on a U.S. or a non-U.S. exchange.

#### Principal Investments

The Exchange states that, under normal market conditions,<sup>7</sup> at least 80% of the Fund's net assets in the following U.S. and non-U.S. exchange-traded real estate securities: Real estate investment trusts ("REITs"), real estate operating companies ("REOCs") and common stocks or "Depositary Receipts" of companies primarily engaged in the real estate industry (collectively, "Real Estate Securities").<sup>8</sup> The Fund may invest in non-U.S. securities (including securities of certain non-U.S. companies), which include securities issued or guaranteed by companies

found in the Notice and the Registration Statement, as applicable. See Notice, *supra* note 3, and Registration Statement, *infra* note 6.

<sup>6</sup> The Exchange states that the Trust is registered under the 1940 Act. According to the Exchange, on August 27, 2014, the Trust filed an amendment to the Trust's registration statement on Form N-1A under the Securities Act of 1933 (the "1933 Act") (15 U.S.C. 77a), and under the 1940 Act relating to the Fund (File Nos. 333-174332 and 811-22559) (the "Registration Statement"). The Exchange states that the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. See Investment Company Act Release No. 28468 (October 27, 2008) (File No. 812-13477).

<sup>7</sup> The term "under normal market conditions" includes, but is not limited to, the absence of extreme volatility or trading halts in the equity markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

<sup>8</sup> The Fund's investments in Real Estate Securities and certain non-U.S. companies (as referred to below under "Non-Principal Investments") may be in the form of Depositary Receipts, which include American Depositary Receipts, Global Depositary Receipts, and European Depositary Receipts. All Depositary Receipts in which the Fund invests will be traded on a U.S. or a non-U.S. exchange.

<sup>24</sup> 17 CFR 200.30-3(a)(12).

organized under the laws of countries other than the United States (including emerging markets). Certain Real Estate Securities in which the Fund invests may be restricted securities (Rule 144A securities).<sup>9</sup> During the initial invest-up period, the Fund may depart from its principal investment strategies and invest a larger amount or all of its assets in cash equivalents or it may hold cash.

#### *Other Investments*

According to the Exchange, the Fund, under normal market conditions, will invest up to 20% of the value of its net assets (plus borrowings for investment purposes) in the following securities and financial instruments described below.

Equity securities, other than Real Estate Securities, in which the Fund will invest may include common and preferred stocks. The Fund may also invest in warrants and rights related to common stocks, preferred equity securities and restricted securities (Rule 144A securities) that are not also Real Estate Securities. The Fund may invest in exchange-traded pooled investment vehicles, open-end or closed-end investment company securities, other exchange-traded funds (“ETFs”) and business development companies (“BDCs”) that invest primarily in securities of the types in which the Fund may invest directly.

The Fund may invest in companies that are considered to be “passive foreign investment companies” (“PFICs”), which are generally certain non-U.S. corporations that receive at least 75% of their annual gross income from passive sources (such as interest, dividends, certain rents and royalties or capital gains) or that hold at least 50% of their assets in investments producing such passive income.

Fixed income investments and cash equivalents held by the Fund may include, the following types of investments: (1) U.S. government securities, including bills, notes and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. government agencies or instrumentalities; (2) certificates of deposit issued against funds deposited in a bank or savings and loan association; (3) bankers’ acceptances, which are short-term credit instruments used to finance commercial transactions; (4) repurchase agreements, which involve purchases of debt securities with counterparties that are

deemed by the Adviser to present acceptable credit risks; (5) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (6) commercial paper, which are short-term unsecured promissory notes, including variable rate master demand notes (direct lending arrangements between the Fund and a corporation) issued by corporations to finance their current operations; (7) shares of money market funds.

The Fund may invest in the following types of non-U.S. fixed income securities (including securities of certain non-U.S. companies): Securities issued or guaranteed by companies organized under the laws of countries other than the United States (including emerging markets), securities issued or guaranteed by foreign, national, provincial, state, municipal or other governments with taxing authority or by their agencies or instrumentalities and debt obligations of supranational governmental entities such as the World Bank or European Union. Non-U.S. securities may also include U.S. dollar-denominated debt obligations, such as “Yankee Dollar” obligations (U.S. dollar-denominated obligations issued in the U.S. capital markets by foreign corporations, banks and governments) of foreign issuers and of supra-national government entities.

The Fund also may invest in forward foreign currency exchange contracts.

### **III. Discussion and Commission’s Findings**

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of section 6 of the Act<sup>10</sup> and the rules and regulations thereunder applicable to a national securities exchange.<sup>11</sup> In particular, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act,<sup>12</sup> which requires, among other things, that the Exchange’s rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission notes that the Fund and the Shares must comply with the requirements of NYSE

Arca Equities Rule 8.600 for the Shares to be listed and traded on the Exchange.

The Commission finds that the proposal to list and trade the Shares on the Exchange is consistent with section 11A(a)(1)(C)(iii) of the Act,<sup>13</sup> which sets forth Congress’s finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. According to the Exchange, quotation and last sale information for the Shares and the following U.S. exchange-traded equity securities will be available via the Consolidated Tape Association high-speed line, and from the national securities exchange on which they are listed: Real Estate Securities, common stocks, preferred stocks, warrants, rights, pooled investment vehicles, ETFs, closed end investment company securities, BDCs, and PFICs. In addition, the Portfolio Indicative Value (“PIV”) as defined in NYSE Arca Equities Rule 8.600 (c)(3), will be widely disseminated every 15 seconds throughout the Exchange’s Core Trading Session by one or more major market data vendors. On each business day, before commencement of trading in Shares in the Core Trading Session (as defined in NYSE Arca Equities Rule 7.34(a)(2)), each Fund will disclose on its Web site the Disclosed Portfolio (as defined in NYSE Arca Equities Rule 8.600(c)(2)) that will form the basis for such Fund’s calculation of NAV at the end of the business day.<sup>14</sup> The Fund’s NAV will be determined as of the close of regular trading on the NYSE on each day the NYSE is open for trading. A basket composition file, which will include the security names and share quantities required to be delivered in exchange for the Shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the New York Stock Exchange via the National Securities Clearing Corporation. Information regarding market price and trading volume of the Shares will be

<sup>13</sup> 15 U.S.C. 78k-1(a)(1)(C)(iii).

<sup>14</sup> On a daily basis, the Fund will disclose on the Fund’s Web site the following information regarding each portfolio holding, as applicable to the type of holding: Ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding); the identity of the security, commodity, index or other asset or instrument underlying the holding, if any; maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and the percentage weighting of the holding in the Fund’s portfolio. This information will be publicly available at no charge.

<sup>10</sup> 15 U.S.C. 78f.

<sup>11</sup> In approving this proposed rule change, the Commission notes that it has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>12</sup> 15 U.S.C. 78f(b)(5).

<sup>9</sup> Any such Real Estate Securities will be traded on a non-U.S. exchange and will not be traded on a U.S. exchange.

continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. The Web site for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Commission notes that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.<sup>15</sup> In addition, trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of a Fund may be halted. The Exchange may halt trading in the Shares if trading is not occurring in the securities and/or the financial instruments constituting the Disclosed Portfolio of a Fund, or if other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.<sup>16</sup> Further, the Commission notes that the Reporting Authority that provides the Disclosed Portfolio of the Fund must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-public information regarding the actual components of the portfolio.<sup>17</sup> The Commission notes that the Financial Industry Regulatory Authority ("FINRA"), on behalf of the Exchange,<sup>18</sup>

will communicate as needed regarding trading in the Shares and certain exchange-traded equity securities with other markets and other entities that are members of the Intermarket Surveillance Group ("ISG"), and FINRA, on behalf of the Exchange, may obtain trading information regarding trading in the Shares and certain exchange-traded equity securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and certain exchange-traded equity securities from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees. According to the Exchange, the Adviser, the Sub-Adviser and the Sub-Sub-Advisers are not broker-dealers, but the Adviser is affiliated with First Trust Portfolios L.P., a broker-dealer, and the Sub-Adviser and the Sub-Sub-Advisers are affiliated with Heitman Securities LLC and Heitman UK Limited, each a broker-dealer. The Exchange states that the Adviser, the Sub-Adviser and the Sub-Sub-Advisers have each implemented fire walls with respect to their respective broker-dealer affiliate(s) regarding access to information concerning the composition and/or changes to the portfolio. In the event (a) the Adviser, the Sub-Adviser or either Sub-Sub-Adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer, or (b) any new adviser, sub-adviser or sub-sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, the Exchange states that it will implement a fire wall with respect to its relevant personnel or its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

The Exchange deems the Shares to be equity securities, which renders trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities.

In support of this proposal, the Exchange has made additional representations, including:

(1) The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

(4) Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit ("ETP") Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (b) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (c) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated PIV not be calculated or publicly disseminated; (d) how information regarding the PIV will be disseminated; (e) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

(5) For initial and/or continued listing, the Fund will be in compliance with Rule 10A-3<sup>19</sup> under the Act, as provided by NYSE Arca Equities Rule 5.3.

(6) A minimum of 100,000 Shares for the Fund will be outstanding at the commencement of trading on the Exchange.

(7) Not more than 10% of the net assets of the Fund in the aggregate invested in equity securities (other than non-exchange-traded investment company securities) shall consist of equity securities whose principal market is not a member of the ISG or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement.

This approval order is based on all of the Exchange's representations.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with section 6(b)(5) of the Act<sup>20</sup> and the rules and

<sup>15</sup> See NYSE Arca Equities Rule 8.600(d)(1)(B).

<sup>16</sup> See NYSE Arca Equities Rule 8.600(d)(2)(C) (providing additional considerations for the suspension of trading in or removal from listing of Managed Fund Shares on the Exchange). With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of each Fund. Trading in Shares of a Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

<sup>17</sup> See NYSE Arca Equities Rule 8.600(d)(2)(B)(ii).

<sup>18</sup> The Exchange states that, while FINRA surveils trading on the Exchange pursuant to a regulatory services agreement, the Exchange is responsible for FINRA's performance under this regulatory services agreement.

<sup>19</sup> 17 CFR 240.10A-3.

<sup>20</sup> 15 U.S.C. 78f(b)(5).

regulations thereunder applicable to a national securities exchange.

#### IV. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 1 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](mailto:rule-comments@sec.gov). Please include File Number SR-NYSEArca-2015-77 on the subject line.

##### *Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NYSEArca-2015-77. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2015-77 and should be submitted on or before November 16, 2015.

#### V. Accelerated Approval of Proposed Rule Change as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice in the **Federal Register**. Amendment No. 1 supplements the proposed rule change by, among other things, clarifying the scope of the Fund's permitted investments and adding additional information about the availability of prices for the Shares and underlying assets. This new information aided the Commission in evaluating the likelihood of effective arbitrage in the Shares. Accordingly, the Commission finds good cause, pursuant to section 19(b)(2) of the Act,<sup>21</sup> to approve 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,<sup>22</sup> that the proposed rule change (SR-NYSEArca-2015-77), as modified by Amendment No. 1, be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>23</sup>

**Brent J. Fields**,  
Secretary.

[FR Doc. 2015-27073 Filed 10-23-15; 8:45 am]

**BILLING CODE 8011-01-P**

#### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76196; File No. SR-ICEEU-2015-017]

#### Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Clearing Services for European Natural Gas Spot Contracts

October 20, 2015.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on October 9, 2015, ICE Clear Europe Limited ("ICE Clear Europe") filed with the Securities and Exchange Commission ("Commission") the proposed rule change described in Items I, II and III

below, which Items have been primarily prepared by ICE Clear Europe. ICE Clear Europe filed the proposal pursuant to section 19(b)(3)(A) of the Act,<sup>3</sup> and Rule 19b-4(f)(4)(ii)<sup>4</sup> thereunder, so that the proposal was 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 principal purpose of the rule change is to amend certain provisions of the ICE Clear Europe rules and procedures that address clearing services for European natural gas spot contracts.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICE Clear Europe 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

ICE Clear Europe has agreed to act as the clearing organization for certain natural gas spot contracts (the "Natural Gas Spot Contracts") traded on the ICE Endex Gas B.V. ("ICE Endex Continental") and ICE Endex Gas Spot Ltd. ("ICE Endex UK") markets and has previously adopted amendments to its Rules and Procedures with respect to the clearing of such contracts.<sup>5</sup> ICE Clear Europe is proposing to adopt certain additional amendments to its Rules and Procedures with respect to the clearing of the Natural Gas Spot Contracts to clarify certain delivery procedures and related arrangements, including with respect to the interaction with relevant gas delivery facilities and systems. These amendments reflect input from Clearing Members and other market participants with respect to the Natural Gas Spot Contracts. ICE Clear

<sup>21</sup> 15 U.S.C. 78s(b)(2).

<sup>22</sup> 15 U.S.C. 78s(b)(2).

<sup>23</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>4</sup> 17 CFR 240.19b-4(f)(4)(ii).

<sup>5</sup> Exchange Act Release No. 34-75170 (June 15, 2015) (File No. SR-ICEEU-2015-011), 80 FR 35418 (June 19, 2015) (the "Initial Spot Contract Filing").

Europe also proposes to adopt certain other conforming and clarifying changes, as discussed herein. ICE Clear Europe submits revisions to Parts 1, 7 and 22 of its Rules and Parts D, E, J and N of the Delivery Procedures.

In the Rules, the revisions to definitions in parts 1 and 22 correct cross-references to certain definitions in the ICE Endex Continental market rules. In Rule 106(a), a clarification is made that disclosures of information may be made by ICE Clear Europe pursuant to obligations imposed on a Market under relevant gas delivery system rules. In Rule 703, which relates to settlement of physically settled futures contracts, Rule 703(h) is modified to clarify ICE Clear Europe's ability to require cash settlement (as may be provided in the relevant Delivery Procedures) where grounds for declaring an Event of Default or Force Majeure Event have occurred with respect to a Clearing Member, but without actually declaring an Event of Default. This approach reflects practices for gas and other relevant markets.

In part D of the Delivery Procedures, which relates to delivery of ICE Futures UK Natural Gas Daily Futures Contracts, clarifications have been made to the timing of certain requirements, including the deadline for submission of certain documentation.

In part E of the Delivery Procedures, various definitions relating to different types of ICE Endex UK natural gas spot contracts have been added or clarified. In addition, delivery responsibilities of transferors and transferees, and related delivery procedures, for the different types of ICE Endex UK spot contracts have been further specified. The amendments in particular address modifications the transferor or transferee (as applicable) may make to the amount of gas to be delivered to or offtaken from the relevant system, and provide that ICE Clear Europe is not responsible for such modifications. The amendments also correct an incorrect reference to ICE Clear Europe as making certain trade nominations with respect to gas delivery.

In part J of the Delivery Procedures, which relates to delivery of ICE Endex Continental gas spot contract, the amendments provide that ICE Endex Continental will submit trade nominations on behalf of ICE Clear Europe and Clearing Members, as applicable, with respect to gas deliveries. The amendments also clarify the applicable responsibilities of the nominated transferor and transferee with respect to delivery.

In part N of the Delivery Procedures (relating to U.S. Emissions contracts),

relevant terminology has been changed from "Position Day" and "Notice Day" to "Notice Day" and "Delivery Instruction Day" to conform to relevant exchange rules.

## 2. Statutory Basis

ICE Clear Europe believes that the proposed rule change is consistent with the requirements of section 17A of the Act<sup>6</sup> and the regulations thereunder applicable to it, including the standards under Rule 17Ad-22,<sup>7</sup> and in particular are consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions cleared by ICE Clear Europe, the safeguarding of securities and funds in the custody or control of ICE Clear Europe and the protection of investors and the public interest, within the meaning of section 17A(b)(3)(F) of the Act.<sup>8</sup> Specifically, the amendments will further specify certain arrangements related to delivery of Natural Gas Spot Contracts cleared by ICE Clear Europe, as well as make certain other clarifying and conforming changes. As discussed in the Initial Spot Contract Filing, the Natural Gas Spot Contracts are spot contracts in natural gas commodities that underlie natural gas futures and options contracts traded on the ICE Endex markets and cleared by ICE Clear Europe, and present a similar risk profile to other ICE Endex contracts currently cleared by ICE Clear Europe. As a result, in ICE Clear Europe's view, its existing financial safeguards and resources, risk management, systems and operational arrangements are sufficient to support clearing of such products (and address physical delivery under such products). The proposed amendments are intended to make additional clarifying changes to support clearing of the Natural Gas Soot [*sic*] Contracts, consistent with these resources, systems and arrangements. The amendments in particular address certain aspects of the delivery under such contracts, and clarify certain default management arrangements applicable to such contracts, as discussed above. The other changes set forth in the proposed rules herein are similarly of a clarifying and conforming nature. As such, in ICE Clear Europe's view, the amendments are consistent with the prompt and accurate clearance and settlement of securities and derivative agreements, contracts and

transactions, within the meaning of the Act.

## B. Self-Regulatory Organization's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule and procedure changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act. As discussed in the Initial Spot Contract Filing, ICE Clear Europe does not believe that clearing of the Natural Gas Spot Contracts, or the changes to the clearing arrangements made in the proposed amendments to the Rules and Procedures, would adversely affect access to clearing for clearing members or their customers or other market participants, or materially and adversely affect the cost of clearing for market participants. Similarly, ICE Clear Europe does not believe the proposed change would otherwise adversely affect competition among clearing members or for clearing services generally.

## C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed changes to the rules have not been solicited or received. ICE Clear Europe will notify the Commission of any written comments received by ICE Clear Europe.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to section 19(b)(3)(A)<sup>9</sup> of the Act and Rule 19b-4(f)(4)(ii)<sup>10</sup> thereunder because it effects a change in an existing service of a registered clearing agency that primarily affects the clearing operations of the clearing agency with respect to products that are not securities, including futures that are not security futures, swaps that are not security-based swaps or mixed swaps, and forwards that are not security forwards, and does not significantly affect any securities clearing operations of the clearing agency or any rights or obligations of the clearing agency with respect to securities clearing or persons using such securities-clearing service. 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

<sup>6</sup> 15 U.S.C. 78q-1.

<sup>7</sup> 17 CFR 240.17Ad-22.

<sup>8</sup> 15 U.S.C. 78q-1(b)(3)(F).

<sup>9</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>10</sup> 17 CFR 240.19b-4(f)(4)(ii).

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](mailto:rule-comments@sec.gov). Please include File Number SR-ICEEU-2015-017 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-ICEEU-2015-017. 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 filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's Web site at <https://www.theice.com/clear-europe/regulation#rule-filings>.

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-ICEEU-2015-017 and

should be submitted on or before November 16, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>11</sup>

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015-27067 Filed 10-23-15; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

### Sunshine Act Meeting

**FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT:** [80 FR 64038, October 22, 2015].

**STATUS:** Oral Argument.

**PLACE:** 100 F Street NE., Washington, DC.

**DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING:** October 26, 2015.

**CHANGE IN THE MEETING:** Room Change. The Oral Argument scheduled for Monday, October 26, 2015 at 1:00 p.m. will be held in the Closed Commission Hearing (Room 10800).

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 551-5400.

Dated: October 22, 2015.

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015-27357 Filed 10-22-15; 4:15 pm]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34-76199; File No. SR-BX-2015-057]**

### Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Implement An Order Exposure Alert To Be Disseminated by the Exchange

October 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on October 6, 2015, NASDAQ OMX BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or

"Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to implement an order exposure alert to be disseminated by the Exchange when a marketable order is placed on the book at a price that locks or crosses the national best bid or offer ("NBBO") when the Exchange is not part of the NBBO.

The text of the proposed rule change is available on the Exchange's Web site at <http://nasdaqomxbx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

#### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

The Exchange is proposing to amend rulebook Chapter VI, Section 11 to implement an order exposure alert in order to provide marketable orders an additional opportunity for execution on the Exchange when the Exchange is not part of the NBBO contra to the order and the order locks or crosses the away best bid or offer ("ABBO").<sup>3</sup>

<sup>3</sup> Similar functionality currently exists on NASDAQ OMX PHLX. See Securities Exchange Act Release No. 68517 (December 21, 2012), 77 FR 77134 (December 31, 2012) (SR-Phlx-2012-136).

<sup>11</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

The Trading System provides two routing options, SEEK<sup>4</sup> and SRCH,<sup>5</sup> pursuant to which orders are sent to other available market centers for potential execution per the entering market participant's instructions. With SEEK and SRCH, an order will first check the System for available contracts for execution. After checking the System for available contracts, orders are sent to other available market centers for potential execution, per the entering firm's instructions. Alternatively, Participants can designate orders as not available for routing.

Currently, when the Exchange's disseminated bid or offer is inferior to the ABBO and an order that is marketable against the ABBO is received, it is matched against any possible contra side orders available in the Trading System. If a routable order is still unexecuted, or if only partially executed, it is then routed away to the market or markets at the ABBO, cancelled back to the entering party or posted on the book and displayed at a non-locking price according to the instructions on the order.<sup>6</sup>

The Exchange is now proposing to amend rulebook Chapter VI, Section 11 to implement an order exposure alert in order to provide marketable orders an

<sup>4</sup> SEEK is a routing option pursuant to which an order will first check the System for available contracts for execution. After checking the System for available contracts, orders are sent to other available market centers for potential execution, per the entering firm's instructions. When checking the book, the System will seek to execute at the price at which it would send the order to a destination market center. Eligible unexecuted orders continue to be routed as described in paragraph (a)(1)(C) of Chapter VI, Section 11. If contracts remain unexecuted after routing, they are posted on the book at the order's limit price. While on the book at the limit price, should the order subsequently be locked or crossed by another market center, the system will not route the order to the locking or crossing market center. SEEK orders will not be eligible for routing until the next time the option series is subject to a new opening or reopening. See Chapter VI, Section 11(a)(1)(A).

<sup>5</sup> SRCH is a routing option pursuant to which an order will first check the System for available contracts for execution. After checking the System for available contracts, orders are sent to other available market centers for potential execution, per the entering firm's instructions. When checking the book, the System will seek to execute at the price at which it would send the order to a destination market center. Eligible unexecuted orders will continue to be routed as described in paragraph (a)(1)(C) of Chapter VI, Section 11. If contracts remain unexecuted after routing, they are posted on the book. Once on the book, should the order subsequently be locked or crossed by another market center, it will re-route. See Chapter VI, Section 11(a)(1)(B).

<sup>6</sup> Because the System routes the lesser of the disseminated size of the away markets or the order size, it is possible for a portion of an order to be routed rather than the entire order. Also, respecting the part of an order that is routed, that order can either be executed in full, in part, or not at all on the destination exchange.

additional opportunity for execution on the Exchange when the Exchange is not part of the NBBO and the order locks or crosses the ABBO. The order exposure alert will apply to both SEEK and SRCH orders and is similar to the order exposure alert process already in place on NASDAQ OMX PHLX ("Phlx").<sup>7</sup> The Exchange has recently amended its rules to specify that *after* an order is initially routed, the order will post to the book and will be routed after a time period ("Route Timer") not to exceed one second as specified by the Exchange on its Web site, provided that the order's price would not lock or cross other market centers.<sup>8</sup> The proposed amendments would permit the Exchange to apply the Route Timer prior to the *initial* routing of the order.

The Exchange proposes to amend Chapter VI, Section 11(1)(A) to provide that a SEEK order remaining on the book after the opening process or received during open trading that is marketable against the ABBO when the ABBO is better than the displayed Exchange BBO will initiate a Route Timer not to exceed one second, and expose the SEEK order at the NBBO to allow market participants an opportunity to interact with the SEEK order. During the Route Timer, the SEEK order will be included in the displayed Exchange BBO at the better of a price one MPV away from the ABBO or the established Exchange BBO. If, during the Route Timer, any new interest arrives opposite the SEEK order that is equal to or better than the ABBO price, the SEEK order will trade against such new interest at the ABBO price.<sup>9</sup> While on the book at the limit price, should a SEEK order subsequently be locked or crossed by another market center, the System will not re-expose

<sup>7</sup> See Phlx Rule 1080(m), Away Markets and Order Routing, Section (iv).

<sup>8</sup> See Securities Exchange Act Release No. 73541 (November 6, 2014) 79 FR 67526 (November 13, 2014) (SR-BX-2014-055). The Exchange is proposing to amend Section (a)(1)(C) by redesignating it as Section (a)(1)(D), and by clarifying in the first and last sentences of that Section that the order will be exposed prior to routing pursuant to that Section. This amendment reflects the fact that order exposure occurs (during open trading) every time an order becomes marketable against the ABBO.

<sup>9</sup> The rule currently states that "[a]fter checking the System for available contracts, orders are sent to other available market centers for potential execution per the entering firm's instructions." This general sentence is being deleted in view of the greater specificity of the proposed new language, and to conform the Exchange's rule language more closely to that of Phlx. The preceding sentence, for clarity, is then amended to provide that after checking the System an order is sent to other available market centers for potential execution.

the order. An order exposure alert may be sent if the order size is modified.

The Exchange also proposes to amend Chapter VI, Section 11(1)(B), to provide that a SRCH order remaining on the book after the opening process or received during open trading that is marketable against the ABBO when the ABBO is better than the displayed Exchange BBO will initiate a Route Timer not to exceed one second, and expose the SRCH order at the NBBO to allow market participants an opportunity to interact with the remainder of the SRCH order. During the Route Timer, the SRCH order will be included in the displayed Exchange BBO at the better of a price one MPV away from the ABBO or the established Exchange BBO. If, during the Route Timer, any new interest arrives opposite the SRCH order that is equal to or better than the ABBO price, the SRCH order will trade against such new interest at the ABBO price.<sup>10</sup> Once on the book, should a SRCH order subsequently be locked or crossed by another market center, it will be re-exposed, provided it is not on the book at its limit price, and re-route. An order exposure alert may be sent if the order size is modified.

The Exchange proposes to redesignate existing Section 11(a)(1)(C) as Section 11(a)(1)(D) and to add new Section 11(a)(1)(C) dealing with Do Not Route or "DNR" Orders. Currently, Section 11(a) provides that Participants can designate orders as not available for routing. The new rule provides additional specificity regarding the Exchange's treatment of such orders, known as DNR orders, tracking language regarding DNR orders from the Phlx rules.<sup>11</sup> The new language clarifies that DNR orders will never be routed outside of the Exchange regardless of the prices displayed by away markets. It specifies that a DNR order may execute on the Exchange at a price equal to or better than, but not inferior to, the best away market price but, if that best away market remains, the DNR order will remain in the Exchange book and be displayed at the better of a price one minimum price variation away from that away best bid/offer or the established Exchange BBO. The new rule states that a DNR order remaining on the book after the opening process or received during open trading that is marketable against the ABBO when the ABBO is better than the Exchange BBO will be exposed at the NBBO to market participants and that any incoming order interacting with such a resting DNR order will receive the best away market price. Should the

<sup>10</sup> *Id.*

<sup>11</sup> See Phlx Rule 1080(m)(iv)(a).



best away market change its price, or move to an inferior price level, the DNR order will automatically re-price from its one minimum price variation away from the original away best bid/offer price to one minimum trading increment away from the new away best bid/offer price or its original limit price, and expose such orders at the NBBO to market participants only if the re-priced order locks or crosses the ABBO and is not already displayed at its limit price. Should the best away market improve its price such that it locks or crosses the DNR order limit price, the Exchange will execute the resulting incoming order that is routed from the away market that locked or crossed the DNR order limit price. An order exposure alert may be sent if the order size is modified.

The Exchange proposes to amend existing paragraph 11(a)(1)(C) which is being redesignated as paragraph 11(a)(1)(D). The amendments state that SEEK and SRCH orders will also be exposed prior to being re-routed at the end of the Route Timer provided for in that paragraph. Thus, the first sentence of that paragraph will be revised to provide that after an order is initially routed, pursuant to either the SEEK or SRCH routing option the order will post to the book and will be exposed and routed after a time period ("Route Timer") not to exceed one second as specified by the Exchange on its Web site provided that the order's limit price would lock or cross other market center(s). Similarly, the final sentence of the paragraph will be amended to state that if an order was routed with either the SEEK or SRCH routing option, and has size after such routing, it will execute against contra side interest in the book, post in the book, and be exposed and route again pursuant to the process described above, if applicable, if the order's limit price would lock or cross another market center(s).

Finally, the Exchange is amending Chapter VI, Trading Systems, Section 1, Definitions, subsection (g)(2) which defines "Immediate or Cancel" or "IOC" as a time in force which means, for orders so designated, that if after entry into the System a marketable order (or unexecuted portion thereof) becomes non-marketable, the order (or unexecuted portion thereof, is canceled and returned to the entering participant. The Exchange is deleting the last sentence of the definition, which currently states that "IOC orders can be routed if designated as routable." The Exchange has determined that IOC orders will be cancelled immediately if not executed, and will not be routed.

IOC orders are currently handled in this manner on Phlx.<sup>12</sup>

## 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act<sup>13</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act<sup>14</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The Exchange believes that exposing certain orders has the potential to result in more efficient executions for customers as responses to exposed orders could result in faster executions. Exposing the order to all market participants should promote broader awareness of, and provide increased opportunities for greater participation in, these executions, facilitating the ability of the Exchange to bring together participants and encourage more robust competition for these orders. In addition, the proposal would continue to guarantee that orders will receive an execution that is at a price at least as good as the price disseminated by the best away market at the time the order was received. The Exchange believes that because all Exchange participants have the ability to subscribe to a data feed to provide them with the notifications exposing the orders, all market participants may avail themselves of the same information.

### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposal should facilitate the ability of the Exchange to bring together market participants and encourage more robust competition.

### 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.

<sup>12</sup> See Phlx Rule 1080(m), Away Markets and Order Routing, the second sentence of the introductory paragraph.

<sup>13</sup> 15 U.S.C. 78f(b).

<sup>14</sup> 15 U.S.C. 78f(b)(5).

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>15</sup> and subparagraph (f)(6) of Rule 19b-4 thereunder.<sup>16</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. 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](mailto:rule-comments@sec.gov). Please include File Number SR-BX-2015-057 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-BX-2015-057. 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/>

<sup>15</sup> 15 U.S.C. 78s(b)(3)(a)(iii).

<sup>16</sup> 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.



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-BX-2015-057 and should be submitted on or before November 16, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>17</sup>

**Brent J. Fields,**  
Secretary.

[FR Doc. 2015-27070 Filed 10-23-15; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76198; File No. SR-NYSEArca-2015-58]

### Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving Proposed Rule Change, and Notice of Filing and Order Granting Accelerated Approval of Amendment No. 1 Thereto, Adopting New Equity Trading Rules Relating to Trading Halts, Short Sales, Limit Up-Limit Down, and Odd Lots and Mixed Lots To Reflect the Implementation of Pillar, the Exchange's New Trading Technology Platform

October 20, 2015.

#### I. Introduction

On July 1, 2015, NYSE Arca, Inc. (the "Exchange" or "Arca") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4

thereunder,<sup>2</sup> a proposed rule change to adopt new equity trading rules relating to Trading Halts, Short Sales, Limit Up-Limit Down, and Odd Lots and Mixed Lots to reflect the implementation of Pillar, the Exchange's new trading technology platform. The proposed rule change was published for comment in the **Federal Register** on July 16, 2015.<sup>3</sup> The Commission received no comment letters on the proposed rule change. On September 1, 2015, pursuant to Section 19(b)(2) of the Act,<sup>3</sup> 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 approve or disapprove the proposed rule change.<sup>4</sup> On October 15, 2015, the Exchange filed Amendment No. 1 to the proposal.<sup>5</sup> The Commission is publishing this notice to solicit comment on Amendment No. 1 from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

#### II. Description of the Proposed Rule Change

The Exchange proposes to adopt new equity trading rules relating to the implementation of Pillar, the Exchange's new trading technology platform. The Exchange proposes to adopt the following new Pillar rules: (1) Definition of "Official Closing Price" (NYSE Arca Equities Rule 1.1 ("Rule 1.1")); (2)

<sup>2</sup> 17 CFR 240.19b-4

<sup>3</sup> See Securities Exchange Act Release No. 75467 (July 22, 2015), 80 FR 43515 ("Notice").

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> See Securities Exchange Act Release No. 75800, 80 FR 53911 (September 8, 2015).

<sup>6</sup> In Amendment No. 1, the Exchange: (i) Removes an erroneous reference to subparagraph (6) from proposed Rule 7.11P(b); (ii) amends proposed Rule 7.16P(f)(5)(A) to add the phrase "or lower than" to clarify that short sale orders with a working price and/or display price below the NBB would also be re-priced to a Permitted Price; (iii) amend proposed Rule 7.16P(f)(5)(C) to clarify that the Exchange would treat all odd lot orders ranked Priority 2—Display Orders in the same manner as Market Orders and other non-displayed orders; (iv) amend proposed Rule 7.16P(f)(5)(D) to provide that all Pegged Orders and MPL Orders, including orders marked buy, sell long, and sell short exempt, would use the NBBO instead of the PBBO as the reference price; (v) amend proposed Rule 7.18P(b)(6) to specify that the Exchange would reject all "incoming order instructions" during a UTP Regulatory Halt other than those specified in proposed Rules 7.18P(b)(1)–(5); (vi) amend footnote 44 of the Notice to add a reference to Limit IOC Orders designated with an MTS, change the rule reference for MPL-IOC Orders from Rule 7.31P(c)(3)(E) to Rule 7.31P(d)(3)(E), and add a reference to Day ISO ALO Orders; and (vii) amend Rule 7.38P(b)(1) to add that if the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), and the PBBO is crossed, it would have a working price equal to the PBB (PBO) to ensure that an odd lot order to buy (sell) would not have a working price below (above) the PBB (PBO).

Clearly Erroneous Executions (NYSE Arca Equities Rule 7.10P ("Rule 7.10P")); (3) Limit Up—Limit Down Plan and Trading Pauses in Individual Securities Due to Extraordinary Market Volatility (NYSE Arca Equities Rule 7.11P ("Rule 7.11P")); (4) Short Sales (NYSE Arca Equities Rule 7.16P ("Rule 7.16P")); (5) Trading Halts (NYSE Arca Equities Rule 7.18P ("Rule 7.18P")); and (6) Odd and Mixed Lots (NYSE Arca Equities Rule 7.38P ("Rule 7.38P")). In addition, the proposed new rules to support Pillar in this filing would use the terms and definitions that were proposed in the Pillar I Filing and Pillar II Filing.<sup>7</sup> The Exchange also proposes to amend existing definitions in Rule 1.1.

#### A. Background

The Exchange represents that Pillar is an integrated trading technology platform designed to use a single specification for connecting to the equities and options markets operated by Arca and its affiliates, New York Stock Exchange LLC ("NYSE") and NYSE MKT LLC ("NYSE MKT").<sup>8</sup> On April 30, 2015, the Exchange filed its first rule filing relating to the implementation of Pillar, which proposed to adopt new rules relating to Trading Sessions, Order Ranking and Display, and Order Execution.<sup>9</sup> On June 26, 2015, the Exchange filed the second rule filing relating to the implementation of Pillar to adopt new rules relating to Orders and Modifiers and the Retail Liquidity Program.<sup>10</sup>

This filing is the third set of proposed rule changes to support Pillar implementation. As proposed, the new rules governing trading on Pillar would have the same numbering as current rules, but with the modifier "P" appended to the rule number. The Exchange proposes that rules with a "P" modifier would operate for symbols that are trading on the Pillar trading platform. If a symbol is trading on the Pillar trading platform, a rule with the same number as a rule with a "P" modifier would no longer operate for

<sup>6</sup> Rule 7.11 and proposed Rule 7.11P implement the Plan to Address Extraordinary Market Volatility pursuant to Rule 608 of Regulation NMS ("LULD Plan"). See Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (File No. 4-631) (Order approving the LULD Plan).

<sup>7</sup> See *infra* notes 9 and 10.

<sup>8</sup> See Notice at 43516.

<sup>9</sup> See Securities Exchange Act Release No. 74951 (May 13, 2015), 80 FR 28721 (May 19, 2015) (SR-NYSEArca-2015-38) ("Pillar I Filing"). The Commission approved the Pillar I Filing on July 20, 2015. See Securities Exchange Act Release No. 75494 (July 20, 2015), 80 FR 44170 (July 24, 2015).

<sup>10</sup> See Securities Exchange Act Release No. 75497 (July 21, 2015), 80 FR 45022 (July 28, 2015) (notice of SR-NYSEArca-2015-56) ("Pillar II Filing").

<sup>17</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

that symbol and the Exchange would announce by Trader Update when symbols are trading on the Pillar trading platform. Definitions that do not have a companion version with a "P" modifier would continue to operate for all symbols.

### B. Proposed Modifications

As described in detail in the Notice, Rules 7.10P, 7.11P, 7.16P, 7.18P, and 7.38P incorporate much of the substance of current NYSE Arca Rules 7.10, 7.11, 7.16, 7.18, and 7.38, respectively. However, with Pillar, the Exchange would introduce new terminology, reorganize and redraft certain provisions to improve clarity, and provide additional detail to other current provisions being redesignated. The Exchange also proposes to make several changes that are more substantive in nature, as follows:

- Adopt a new definition in Pillar to define the term "Official Closing Price," which would mean the reference price to determine the closing price in a security for purposes of Rule 7 Equities Trading;<sup>11</sup>
- during Core Trading Hours, the Exchange would halt trading during a UTP Regulatory Halt until it receives the first Price Band in a UTP Security;<sup>12</sup>
  - the Exchange would not conduct any Trading Halt Auctions in UTP Securities;<sup>13</sup>
  - Pegged Orders would not be cancelled during a UTP Regulatory Halt;<sup>14</sup>
  - During a UTP Regulatory Halt, the Exchange would process a request to cancel and replace as a cancellation without replacing the order;<sup>15</sup>
  - During a UTP Regulatory Halt, the Exchange would accept and route new

<sup>11</sup> See proposed Rule 1.1(ggP); see also Notice at 43517. Proposed Rule 1.1(ggP)(1) would describe how the Official Closing Price would be determined for securities listed on the Exchange. As proposed, the Official Closing Price would be the price established in a Closing Auction of one round lot or more on a trading day. Because there may be circumstances when there is insufficient trading interest to have a closing auction trade of one round lot or more, the Exchange proposes to specify what price the Exchange would use as its Official Closing Price when there is no auction or a closing trade of less than a round lot. As proposed, if there is no Closing Auction or if a Closing Auction trade is less than a round lot on a trading day, the Official Closing Price would be the most recent consolidated last sale eligible trade during Core Trading Hours on that trading day. The rule would further provide that if there were no consolidated last sale eligible trades during Core Trading Hours on that trading day, the Official Price would be the prior trading day's Official Closing Price.

<sup>12</sup> See proposed Rule 7.18P(a); see also Notice at 43518.

<sup>13</sup> See proposed rule 7.18P(b)(1); see also Notice at 43518.

<sup>14</sup> See *id.*

<sup>15</sup> See proposed rule 7.18P(b)(4); see also Notice at 43519.

Market Orders, Auction-Only Orders, Primary Only Market-on-Open ("MOO")/Limit on Open ("LOO") Orders, Primary Only Day Orders, and Primary Only Market-on-Close ("MOC")/Limit-on-Close ("LOC") Orders to the primary listing market;<sup>16</sup>

- As described more fully in the Notice, because Exchange-listed securities would be eligible to participate in a Trading Halt Auction, the Exchange proposes to process orders in Exchange-listed securities differently than how it would process orders in UTP Securities;<sup>17</sup>

- As described more fully in the Notice, because of proposed substantive differences to how certain orders and modifiers would operate, the Exchange proposes different handling of certain orders in Pillar to comply with the requirements of Rule 201 of Regulation SHO ("Rule 201");<sup>18</sup>

- The Exchange would use the Official closing Price for purposes of determining the Trigger Price for the Short Sale Price Test in exchange-listed securities;<sup>19</sup>

- An Exchange Trading Permit ("ETP") Holder's instruction to reject back individual short sale orders subject to the short sale price test would apply to resting orders;<sup>20</sup> and

- As described more fully in the Notice, the Exchange would expand the number of order types that would be eligible for optional re-pricing instructions pursuant to the LULD Plan;<sup>21</sup>

### III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act<sup>22</sup> and the rules and regulations thereunder applicable to a national securities exchange.<sup>23</sup> In particular, the Commission finds that the proposed

<sup>16</sup> See proposed rule 7.18P(b)(5); see also Notice at 43519.

<sup>17</sup> See proposed rule 7.18P(c); see also Notice at 43519.

<sup>18</sup> 17 CFR 242.201. See proposed rule 7.16P; see also Notice at 43520–43523.

<sup>19</sup> See proposed rule 7.16P(f)(2); see also Notice at 43520.

<sup>20</sup> See proposed rule 7.16P(f)(5)(B); see also Notice at 43521.

<sup>21</sup> See proposed rule 7.11P; see also Notice at 43523–43525. In addition, rather than specifying which order types would be eligible for re-pricing instructions, the Exchange would enumerate which order types would not be eligible for repricing instructions. See proposed rule 7.11P(a)(6)(A); see also Notice at 43523–43524.

<sup>22</sup> 15 U.S.C. 78f.

<sup>23</sup> In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

rule change is consistent with Section 6(b)(5) of the Act,<sup>24</sup> 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 foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and that the rules are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission notes that the Exchange believes that the proposed rules would remove impediments to and perfect the mechanism of a free and open market because the proposed rule set would promote transparency by using consistent terminology governing equities trading, and by clearly denoting the rules that govern once a symbol has been migrated to the Pillar platform.<sup>25</sup>

With respect to the proposed changes to Rule 1.1, the Commission notes that the Exchange believes that the proposed amendments would remove impediments to and perfect the mechanism of a fair and orderly market because they would not make any substantive changes to Exchange rules, but rather are designed to reduce confusion by eliminating obsolete references and terms and therefore streamline the Exchange's rules. The Commission also notes that the Exchange further believes that the proposed new definition for the term "Official Closing Price" would remove impediments to and perfect the mechanism of a fair and orderly market because the proposed definition would promote transparency regarding the reference price the Exchange would use in Pillar for purposes of calculating Trading Collars, pursuant to proposed Rule 7.31P(a)(1)(B), and for purposes of determining a Trigger Price pursuant to proposed Rule 7.16P(f)(2).<sup>26</sup>

For determining the Official Closing Price, the Exchange states that it believes that in the absence of a Closing Auction of a round lot or more, the most recent consolidated last sale eligible trade during Core Trading Hours best approximates the market's determination of the appropriate price of such securities.<sup>27</sup> In addition, the

<sup>24</sup> 15 U.S.C. 78f(b)(5).

<sup>25</sup> See Notice at 43526.

<sup>26</sup> See *id.*

<sup>27</sup> See *id.*

Exchange states that it believes that using only those trades that occur during Core Trading Hours that are last sale eligible would remove impediments to and perfect the mechanism of a fair and orderly market because the lower liquidity during the Early and Late Trading Sessions may mean that trades occurring during those sessions may not be as representative of the price of the security and odd-lot trades may indicate an anomalous trade.<sup>28</sup>

With respect to proposed Rule 7.10P, regarding clearly erroneous executions, the Commission notes that the Exchange represents that the proposal would remove impediments to and perfect the mechanism of a fair and orderly market because it would use Pillar terminology, without any substantive differences from current Rule 7.10.<sup>29</sup>

With respect to proposed Rule 7.11P, the Commission notes that the Exchange believes that the proposed substantive difference to expand the number of Limit Orders eligible for re-pricing instructions would be consistent with the LULD Plan, and therefore would remove impediments to and perfect the mechanism of a fair and orderly market, because the proposed re-pricing of such orders would assure that such orders would not trade at or be displayed at prices outside of the Price Bands.<sup>30</sup> The Exchange further states that it believes that expanding the number of orders eligible for re-pricing instructions would provide ETP Holders with more options regarding how orders would be processed in compliance with the LULD Plan.<sup>31</sup> With respect to Mid-Point Liquidity (“MPL”) Orders, the Exchange states that it believes that proposed Rule 7.11P(a)(6)(C) would remove impediments to and perfect the mechanism of a fair and orderly market because the proposal would provide ETP Holders with the choice for such orders not to be cancelled, and instead remain on the NYSE Arca Book until such time that the working price would be at a price eligible to trade consistent with the LULD Plan.<sup>32</sup> The Exchange further believes that using Pillar terminology to describe how orders would be re-priced would promote consistency in Exchange rules, making them easier to navigate.<sup>33</sup>

With respect to Short Sales, the Commission notes that the Exchange represents that proposed Rule 7.16P would remove impediments to and

perfect the mechanism of a fair and orderly market because it would use Pillar terminology to describe how the Exchange would process sell short orders during a Short Sale Period, consistent with Rule 201 of Regulation SHO.<sup>34</sup> More specifically, the Exchange states that it believes that using the new term “Official Closing Price” for determining the Trigger Price of a security in Rule 7.16P(f)(2) is consistent with Rule 201(b)(1)(i) of Regulation SHO, which requires that the listing market determine the closing price of a covered security, but does not require that the Exchange use the closing auction on the Exchange to determine that closing price.<sup>35</sup> Moreover, the Commission notes that the Exchange represents that how it would process sell short orders during a Short Sale Period, set forth in proposed Rule 7.16P(f)(5), would remove impediments to and perfect the mechanism of a fair and orderly market because the proposed processing would assure that sell short orders would neither trade at the National Best Bid (“NBB”) or be displayed at the NBB, unless an order is eligible for an exemption pursuant to proposed Rule 7.16P(f)(6) or (f)(7).<sup>36</sup> The Exchange further represents that the proposed processing in Pillar of odd-lot orders that are ranked Priority 2, Pegged Orders, Cross Orders, and Tracking Orders would remove impediments to and perfect the mechanism of a fair and orderly market and is consistent with Rule 201 of Regulation SHO because the proposed processing would assure that such orders would not trade at the NBB or be displayed at the NBB as the NBB moves both up and down.<sup>37</sup>

With respect to proposed Rule 7.18P, the Commission notes that the Exchange believes that it would remove impediments to and perfect the mechanism of a fair and orderly market because it would set forth in a single rule the requirements for trading halts on the Exchange in both UTP Securities and Exchange-listed securities, which are currently set forth in Rules 7.11(b)(6), 7.18, and 7.34(a)(4) and (a)(5).<sup>38</sup> The Exchange also represents that it believes that the proposed substantive differences for Rule 7.18P as compared to the current rules would remove impediments to and perfect the mechanism of a fair and orderly market.<sup>39</sup> Specifically, the Exchange represents that it believes that waiting

until receipt of a Price Band in a UTP Security before resuming trading following a UTP Regulatory Halt would assure that the Exchange would not begin trading in a UTP Security before the protections of the LULD Plan would be available.<sup>40</sup> In addition, not holding a Trading Halt Auction on the Exchange in a UTP Security, together with rejecting new orders and routing Primary Only Orders received during a UTP Regulatory Halt to the primary listing market, would protect investors and the public by promoting price discovery and liquidity on the primary listing market for its re-opening auction. In addition, the Exchange represents that it believes that processing new and existing orders for UTP Securities differently from new and existing orders in Exchange-listed securities during a halt, suspension, or trading pause would complement the proposal not to conduct a Trading Halt Auction in a UTP Security. For Exchange-listed securities, because the Exchange would be conducting a Trading Halt Auction, the Exchange states that it would accept new orders that would be eligible to participate in such auction. In addition, to facilitate such auction, the Exchange would not cancel resting Pegged Orders and would adjust the working price of resting Limit Orders (including Pegged Orders) to their limit price so that such orders could participate in a Trading Halt Auction at their limit prices. The Exchange represents that it believes such proposed processing of new and existing orders would promote liquidity and price discovery for Trading Halt Auctions in Exchange-listed securities.<sup>41</sup>

With respect to proposed Rule 7.38P, the Commission notes that the Exchange believes that the proposed rule would promote consistency in the Exchange’s rule book by using Pillar terminology to describe how the Exchange would price odd lot orders so that they would not trade through the protected best bid or offer (“PBBO”).<sup>42</sup> The Exchange represents that proposed Rule 7.38P(b)(2) would remove impediments to and perfect the mechanism of a fair and orderly market because it would promote transparency in Exchange rules regarding the working time that would be assigned to an order that has been partially routed and whether, when it returns, it would be displayed as a new best bid or offer (“BBO”).<sup>43</sup>

Based on the Exchange’s representations, the Commission

<sup>28</sup> See *id.*

<sup>29</sup> See Notice at 43527.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> See Notice at 43527.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> See Notice at 43526.

<sup>39</sup> See Notice at 43527.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* See also Amendment No. 1.

<sup>43</sup> See Notice at 43527.

believes that the proposed rule change does not raise any novel regulatory considerations and should provide greater specificity with respect to the functionality available on the Exchange as symbols are migrated to the Pillar platform. For these reasons, the Commission believes that the proposal should help to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest.

#### IV. Accelerated Approval of Amendment No. 1

In Amendment No. 1, the Exchange: (i) Removes an erroneous reference to subparagraph (6) from proposed Rule 7.11P(b); (ii) amends proposed Rule 7.16P(f)(5)(A) to add the phrase “or lower than” to clarify that short sale orders with a working price and/or display price below the NBB would also be re-priced to a Permitted Price; (iii) amends proposed Rule 7.16P(f)(5)(C) to clarify that the Exchange would treat all odd lot orders ranked Priority 2—Display Orders in the same manner as Market Orders and other non-displayed orders; (iv) amends proposed Rule 7.16P(f)(5)(D) to provide that *all* Pegged Orders and MPL Orders, including orders marked buy, sell long, and sell short exempt, would use the national best bid or offer (“NBBO”) instead of the PBBO as the reference price; (v) amend proposed Rule 7.18P(b)(6) to specify that the Exchange would reject all “incoming order instructions” during a UTP Regulatory Halt other than those specified in proposed Rules 7.18P(b)(1)–(5); (vi) amend footnote 44 of the Notice to add a reference to Limit Immediate-or-Cancel (“IOC”) Orders designated with a minimum trade size (“MTS”), change the rule reference for MPL–IOC Orders from Rule 7.31P(c)(3)(E) to Rule 7.31P(d)(3)(E), and add a reference to Day ISO ALO Orders; and (vii) amends Rule 7.38P(b)(1) to add that if the limit price of an odd lot order to buy (sell) is above (below) the protected best offer (“PBO”) (protected best bid (“PBB”), and the PBBO is crossed, it would have a working price equal to the PBB (PBO) to ensure that an odd lot order to buy (sell) would not have a working price below (above) the PBB (PBO).

The Commission believes that the changes proposed in Amendment No. 1 are non-substantive and further clarify the operation of the proposed rules governing Pillar. Accordingly, the Commission finds good cause, pursuant

to Section 19(b)(2) of the Act,<sup>44</sup> to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

#### V. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 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](mailto:rule-comments@sec.gov). Please include File Number SR–NYSEArca–2015–58 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–NYSEArca–2015–58. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2015–58, and should be

<sup>44</sup> 15 U.S.C. 78s(b)(2).

submitted on or before November 16, 2015.

#### VI. Conclusion

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Act,<sup>45</sup> that the proposed rule change (SR–NYSEArca–2015–58), as modified by Amendment No. 1 thereto, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>46</sup>

**Brent J. Fields,**  
*Secretary.*

[FR Doc. 2015–27069 Filed 10–23–15; 8:45 am]

BILLING CODE 8011–01–P

#### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76201; File No. SR–MIAX–2015–59]

#### Self-Regulatory Organizations: Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 404

October 20, 2015.

Pursuant to the provisions of section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b–4 thereunder,<sup>2</sup> notice is hereby given that on October 15, 2015, Miami International Securities Exchange LLC (“MIAX” or “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

The Exchange is filing a proposal to amend Exchange Rule 404 to replace the name “Google Inc.” with “Alphabet Inc.”

The text of the proposed rule change is available on the Exchange’s Web site at [http://www.miaxoptions.com/filter/wotitle/rule\\_filing](http://www.miaxoptions.com/filter/wotitle/rule_filing), at MIAX’s principal office, and at the Commission’s Public Reference Room.

<sup>45</sup> 15 U.S.C. 78s(b)(2).

<sup>46</sup> 17 CFR 200.30–3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b–4.

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The Exchange is proposing to amend Interpretations and Policies .08 to MIA X Rule 404, entitled Mini Option Contracts, to replace the name "Google Inc." with "Alphabet Inc." Google Inc. ("Google") recently announced plans to reorganize and create a new public holding company, which will be called Alphabet Inc. ("Alphabet"). As a result of the holding company reorganization, each share of Class A Common Stock ("GOOGL"), on which the Exchange has the ability to list as a Mini Option, will automatically convert into an equivalent corresponding share of Alphabet Inc. stock. The symbol "GOOGL" remains unchanged.

The Exchange is proposing to make this change to Interpretations and Policies .08 to enable the Exchange to list and trade Mini Options on Google, now Alphabet, Class A shares. The Exchange is proposing to make this change because, on October 5, 2015 Google reorganized and as a result underwent a name change.

The purpose of this change is to ensure that Interpretations and Policies .08 to Exchange Rule 404 reflects the Exchange's intention to be able to list and trade Mini Options on only an exhaustive list of underlying securities outlined in Interpretations and Policies .08 to Rule 404. As a result, the proposed change will help avoid confusion.

#### 2. Statutory Basis

MIA X believes that its proposed rule change is consistent with section 6(b) of the Act<sup>3</sup> in general, and furthers the objectives of section 6(b)(5) of the Act<sup>4</sup> in particular, in that it is designed to

prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

In particular, the proposed rule change to change the name Google to Alphabet to reflect the new ownership structure is consistent with the Act because the proposed change is merely updating the current name associated with the stock symbol GOOGL. The proposed change will allow for continued benefit to investors by enabling the Exchange to provide them with additional investment alternatives.

### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In particular, the proposed rule change to change the name Google to Alphabet to reflect the new ownership structure is consistent with the Act because the proposed change is merely updating the current name associated with the stock symbol GOOGL. The proposed change will allow for continued benefit to investors by enabling the Exchange to provide them with additional investment alternatives.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act<sup>5</sup> and Rule 19b-4(f)(6)<sup>6</sup> thereunder.

<sup>5</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>6</sup> 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule

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](mailto:rule-comments@sec.gov). Please include File Number SR-MIA X-2015-59 on the subject line.

### Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.
- All submissions should refer to File Number SR-MIA X-2015-59. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal

change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

<sup>3</sup> 15 U.S.C. 78f(b).

<sup>4</sup> 15 U.S.C. 78f(b)(5).

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-MIAX-2015-59, and should be submitted on or before November 16, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>7</sup>

**Brent J. Fields,**  
*Secretary.*

[FR Doc. 2015-27072 Filed 10-23-15; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76197; File No. SR-BATS-2015-87]

### Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 11.13, Order Execution and Routing

October 20, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on October 9, 2015, BATS Exchange, Inc. (the “Exchange” or “BATS”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A) of the Act<sup>3</sup> and Rule 19b-4(f)(6) thereunder,<sup>4</sup> which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization’s Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 11.13, Order Execution and Routing, to enable Users<sup>5</sup> to designate their orders for participation in the re-opening (following a halt, suspension,

or pause) of a primary listing market other than the Exchange (NYSE, Nasdaq, NYSE MKT, or NYSE Arca) if received before the re-opening time of such market.

The text of the proposed rule change is available at the Exchange’s Web site at [www.batstrading.com](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 amend Rule 11.13, Order Execution and Routing, to enable Users to designate their orders for participation in the re-opening (following a halt, suspension, or pause) of a primary listing market other than the Exchange (NYSE, Nasdaq, NYSE MKT, or NYSE Arca) if received before the re-opening time of such market. The Exchange currently offers the ROOC routing option, under which Users may designate their orders for participation in the opening or closing process, in addition to the re-opening (following a halt, suspension, or pause), of a primary listing market other than the Exchange, if received before the opening/re-opening/closing time of such market.<sup>6</sup> However, some Users only wish that their orders be routed to participate in the primary market’s re-opening process, and not its opening or closing processes. Therefore, the Exchange proposes to enable Users to designate their orders for participation in the re-opening of a primary listing market.

The proposed optionality would operate like the current ROOC routing option, but for routing to the primary listing market’s opening or closing process. Lastly, like the ROOC routing

option, any remaining shares will either be posted to the BATS Book,<sup>7</sup> executed, or routed to destinations on the System routing table.<sup>8</sup> Should no halt, suspension, or pause occur on the primary listing market, such orders would remain on the BATS Book, executed, or routed to destinations on the System routing table.

###### 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act<sup>9</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act<sup>10</sup> in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Certain Users whose orders are resting on the BATS Book may wish that their order only be routed to the primary market’s re-opening process following a halt, suspension or pause, and not the primary market’s opening or closing processes. The proposed rule change promotes just and equitable principles of trade because it would provide such Users with additional flexibility where they wish that their order only be eligible to route to the primary listing market to participate in the re-opening process following a halt, suspension or pause. In addition, and as discussed above, the proposed rule change is similar to the Exchange’s current ROOC routing option.

##### B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposal will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that its proposal would increase competition because it offers Users an alternative means to route orders to the primary listing market to participate in the re-opening following a halt, suspension, or pause as if they entered orders on that market directly.

<sup>7</sup> The term “BATS Book” is defined as “the System’s electronic file of orders.” See Exchange Rule 1.5(e).

<sup>8</sup> The term “System routing table” refers to the proprietary process for determining the specific options exchanges to which the System routes orders and the order in which it routes them. See Exchange Rule 11.13(b)(3).

<sup>9</sup> 15 U.S.C. 78f(b).

<sup>10</sup> 15 U.S.C. 78f(b)(5).

<sup>7</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>4</sup> 17 CFR 240.19b-4(f)(6).

<sup>5</sup> The term “User” is defined as “any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3.” See Exchange Rule 1.5(cc).

<sup>6</sup> See Exchange Rule 11.13(b)(3)(N).

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange has neither solicited nor received written comments on the proposed rule change.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The Exchange has designated this rule filing as non-controversial under Section 19(b)(3)(A) of the Act<sup>11</sup> and paragraph (f)(6) of Rule 19b-4 thereunder.<sup>12</sup> The proposed rule change effects a change that (A) does not significantly affect the protection of investors or the public interest; (B) does not impose any significant burden on competition; and (C) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest; provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change, 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.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily temporarily suspend such rule change if it appears to the Commission that such action is: (1) Necessary or appropriate in the public interest; (2) for the protection of investors; or (3) 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](mailto:rule-comments@sec.gov). Please include File Number SR-BATS-2015-87 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-BATS-2015-87. 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-2015-87, and should be submitted on or before November 16, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>13</sup>

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015-27068 Filed 10-23-15; 8:45 am]

**BILLING CODE 8011-01-P**

**SMALL BUSINESS ADMINISTRATION**

**Senior Executive Service: Performance Review Board Members**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice of Members for the FY 2016 Performance Review Board.

**SUMMARY:** Title 5 U.S.C. 4314(c)(4) requires each agency to publish notification of the appointment of

individuals who may serve as members of that Agency's Performance Review Board (PRB). The following individuals have been designated to serve on the FY 2016 Performance Review Board for the U.S. Small Business Administration.

1. Delorice Ford, (Chair), Assistant Administrator for Hearings and Appeals
2. Isabella Guzman, Deputy Chief of Staff
3. James Rivera, Associate Administrator for Disaster Assistance
4. Erin Andrew, Assistant Administrator for Women's Business Ownership
5. Eugene Cornelius, Deputy Associate Administrator for Field Operations
6. Francisco Marrero, District Director, South Florida
7. Linda Rusche, Director of Financial Assistance
8. Nicolas Maduros, Chief of Staff

Dated: October 15, 2015.

**Maria Contreras-Sweet,**  
*Administrator.*

[FR Doc. 2015-26665 Filed 10-23-15; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF STATE**

[Public Notice 9327]

**Advisory Committee on International Economic Policy; Notice of Open Meeting**

The Advisory Committee on International Economic Policy (ACIEP) will meet from 2:00 until 5:00 p.m., on Tuesday, November 10, 2015, in Washington, DC at the State Department, 2201 C Street NW., in Conference Room 4477. The meeting will be hosted by the Assistant Secretary of State for Economic and Business Affairs, Charles H. Rivkin and Committee Chair Paul R. Charron. The ACIEP serves the U.S. government in a solely advisory capacity, and provides advice concerning topics in international economic policy. It is expected that the ACIEP subcommittees will provide updates on their work.

This meeting is open to public participation, though seating is limited. Entry to the building is controlled. To obtain pre-clearance for entry, members of the public planning to attend should *no later than Tuesday, November 3*, provide their full name and professional affiliation to Alan Krill by email: [Krilla@state.gov](mailto:Krilla@state.gov). Requests for reasonable accommodation should be made to Alan Krill before Tuesday, November 3. Requests made after that date will be considered, but might not be possible to fulfill.

<sup>11</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>12</sup> 17 CFR 240.19b-4.

<sup>13</sup> 17 CFR 200.30-3(a)(12).



For additional information, contact Alan Krill, Office of Economic Policy Analysis and Public Diplomacy, Bureau of Economic and Business Affairs, at (202) 647-0812, or [Krilla@state.gov](mailto:Krilla@state.gov).

Dated: October 19, 2015.

**Alan Krill,**

*Designated Federal Official, U.S. Department of State.*

[FR Doc. 2015-27151 Filed 10-23-15; 8:45 am]

**BILLING CODE 4710-07-P**

## DEPARTMENT OF STATE

### [Public Notice 9325]

#### Notice of Public Meeting

**SUMMARY:** The U.S. Department of State, Bureau of Oceans and International Environmental and Scientific Affairs (OES), Office of Marine Conservation announces that the Advisory Panel to the U.S. Section of the North Pacific Anadromous Fish Commission will meet on November 23, 2015.

**DATES:** The meeting will take place via teleconference on November 23rd, 2015 from 2 p.m. to 4 p.m. Eastern time.

**Meeting Details:** The teleconference call-in number is toll-free 877-336-1831, passcode 6472335, and will have a limited number of lines for members of the public to access from anywhere in the United States. Callers will hear instructions for using the passcode and joining the call after dialing the toll-free number noted. Members of the public wishing to participate in the teleconference must contact the OES officer in charge as noted in the **FOR MORE INFORMATION** section below no later than close of business on Friday, November 20th, 2015.

**FOR FURTHER INFORMATION CONTACT:** Elana Katz-Mink, Office of Marine Conservation, OES, Room 2758, U.S. Department of State, 2201 C Street NW., Washington, DC 20520. Telephone (202) 647-1073, fax (202) 736-7350, email address [katz-minkeh@state.gov](mailto:katz-minkeh@state.gov).

**SUPPLEMENTARY INFORMATION:** In accordance with the requirements of the Federal Advisory Committee Act, notice is given that the Advisory Panel to the U.S. Section of the North Pacific Anadromous Fish Commission (NPAFC) will meet on the date and time noted above. The panel consists of members from the states of Alaska and Washington who represent the broad range fishing and conservation interests in anadromous and ecologically related species in the North Pacific. Certain members also represent relevant state and regional authorities. The panel was established in 1992 to advise the U.S. Section of the NPAFC on research needs

and priorities for anadromous species, such as salmon, and ecologically related species occurring in the high seas of the North Pacific Ocean. The upcoming Panel meeting will focus on three major topics: (1) Review of the agenda for the 2015 annual meeting of the NPAFC (May 11-15, 2015; Kobe, Japan); and (2) planning for the work of the Advisory Panel in 2016. Background material is available from the point of contact noted above and by visiting [www.npafc.org](http://www.npafc.org).

Dated: October 14, 2015.

**William Gibbons-Fly,**

*Director, Office of Marine Conservation, Department of State.*

[FR Doc. 2015-27150 Filed 10-23-15; 8:45 am]

**BILLING CODE 4710-09-P**

## DEPARTMENT OF STATE

### [Delegation of Authority No. 388]

#### Delegation to Thomas A. Shannon of Authorities Normally Vested in the Under Secretary of State for Political Affairs

By virtue of the authority vested in the Secretary of State by the laws of the United States, including Section 1 of the State Department Basic Authorities Act, as amended (22 U.S.C. 2651a), I hereby delegate to Thomas A. Shannon the authorities and functions of the Under Secretary of State for Political Affairs; as well as, to the extent authorized by law, all authorities and functions that have been or may be delegated to the Under Secretary of State for Political Affairs.

This delegation of authority does not revoke, supersede, or affect any other delegation of authority. Any authority covered by this delegation may also be exercised by the Secretary, the Deputy Secretary, or the Deputy Secretary for Management and Resources.

This delegation shall expire upon the appointment and entry upon duty of an individual to replace Wendy R. Sherman as the Under Secretary of State for Political Affairs.

This delegation of authority shall be published in the **Federal Register**.

Dated: October 14, 2015.

**John F. Kerry,**

*Secretary of State.*

[FR Doc. 2015-27152 Filed 10-23-15; 8:45 am]

**BILLING CODE 4710-10-P**

## TENNESSEE VALLEY AUTHORITY

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Tennessee Valley Authority.

**ACTION:** 30-Day notice of submission of information collection approval and request for comments.

**SUMMARY:** This survey will be used to determine estimates for the numbers annual recreation visits, associated user economic impacts and will target both reservoir and tailwater general recreation users and shoreline property owners. The proposed information collection described below will be submitted to the Office of Management and Budget (OMB) at, [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov), for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended). The Tennessee Valley Authority is soliciting public comments on this proposed collection as provided by 5 CFR 1320.8(d)(1).

**DATES:** Comments should be sent to the Agency Clearance Officer and the OMB Office of Information & Regulatory Affairs, Attention: Desk Officer for Tennessee Valley Authority, Washington, DC, 20503, or email: [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov), no later than November 25, 2015.

**ADDRESSES:** Requests for information, including copies of the information collection proposed and supporting documentation, should be directed to the Agency Clearance Officer: Philip D Propes, Tennessee Valley Authority, 1101 Market Street (SP-5S-108), Chattanooga, Tennessee 37402-2801; (423) 751-8593.

#### SUPPLEMENTARY INFORMATION:

**Type of Request:** Regular request. New collection.

**Title of Information Collection:** TVA Recreation User Survey.

**Frequency of Use:** As funding is available.

**Type of Affected Public:** Individuals or households.

**Small Businesses or Organizations Affected:** No.

**Federal Budget Functional Category Code:** 271.

**Estimated Number of Annual Responses:** 3000.

**Estimated Total Annual Burden Hours:** 1000.0.

**Estimated Average Burden Hours per Response:** .20.

**Need For and Use of Information:** TVA will contract with the University of Tennessee to Survey by mail and in person recreation users on the TVA reservoir system to determine estimates for the numbers annual recreation visits and associated economic impacts from



the recreation activities on the reservoir system.

**Philip D. Propes,**

Director, Enterprise Information Security and Policy.

[FR Doc. 2015-27213 Filed 10-23-15; 8:45 am]

BILLING CODE 8120-08-P

**TENNESSEE VALLEY AUTHORITY**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Tennessee Valley Authority.

**ACTION:** 30-day notice of submission of information collection approval and request for comments.

**SUMMARY:** This survey is used to locate, for monitoring purposes, rural residents, home gardens, and milk animals within a five mile radius of a nuclear power plant. The Land use survey is performed once per year. TVA uses the Land use survey data for their effluent annual report to the NRC normally in April every year. The proposed information collection described below will be submitted to the Office of Management and Budget (OMB) at, *oira\_submission@omb.eop.gov*, for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended). The Tennessee Valley Authority is soliciting public comments on this proposed collection as provided by 5 CFR 1320.8(d)(1).

**DATES:** Comments should be sent to the Agency Clearance Officer and the OMB Office of Information & Regulatory Affairs, Attention: Desk Officer for Tennessee Valley Authority, Washington, DC 20503, or email: *oira\_submission@omb.eop.gov*, no later than November 25, 2015.

**ADDRESSES:** Requests for information, including copies of the information collection proposed and supporting documentation, should be directed to the Agency Clearance Officer: Philip D. Propes, Tennessee Valley Authority, 1101 Market Street (SP-5S-108), Chattanooga, Tennessee 37402-2801; (423) 751-8593.

**SUPPLEMENTARY INFORMATION:**

*Type of Request:* Regular request. Reinstatement, with change, of a previously approved collection for which approval has expired.

*Title of Information Collection:* Land Use Survey Questionnaire—Vicinity of Nuclear Power Plants.

*Frequency of Use:* Annual.

*Type of Affected Public:* Individuals or households, farms and business and other for-profit.

*Small Businesses or Organizations*

*Affected:* Yes.

*Federal Budget Functional Category Code:* 271.

*Estimated Number of Annual Responses:* 150.

*Estimated Total Annual Burden Hours:* 75.0.

*Estimated Average Burden Hours Per Response:* .50.

*Need For and Use of Information:* The monitoring program is a mandatory requirement of the Nuclear Regulatory Commission set out in the technical specifications when the plants were licensed.

**Philip D. Propes,**

Director, Enterprise Information Security and Policy.

[FR Doc. 2015-27226 Filed 10-23-15; 8:45 am]

BILLING CODE 8120-01-P

**TENNESSEE VALLEY AUTHORITY**

**Integrated Resource Plan**

**AGENCY:** Tennessee Valley Authority.

**ACTION:** Issuance of record of decision.

**SUMMARY:** This notice is provided in accordance with the Council on Environmental Quality's regulations (40 CFR 1500 to 1508) and TVA's procedures for implementing the National Environmental Policy Act (NEPA). TVA has decided to adopt the preferred alternative in its final supplemental environmental impact statement (SEIS) for the Integrated Resource Plan (IRP). The notice of availability (NOA) of the *Final Supplemental Environmental Impact Statement for the Integrated Resource Plan* was published in the **Federal Register** on July 17, 2015. The TVA Board of Directors approved the IRP and authorized staff to implement the preferred alternative at its August 21, 2015 meeting. This alternative, the Target Power Supply Mix, will guide TVA's selection of energy resource options to meet the energy needs of the Tennessee Valley region over the next 20 years. The energy resource options include new nuclear, natural gas-fired and renewable generation, increased energy efficiency and demand reduction, and decreased coal-fired generation.

**FOR FURTHER INFORMATION CONTACT:**

Charles P. Nicholson, NEPA Compliance, Tennessee Valley Authority, 400 West Summit Hill Drive, WT 11D, Knoxville, Tennessee 37902-1499; telephone 865-632-3582 or email *cpnicholson@tva.gov*.

Gary S. Brinkworth, IRP Project Manager, Tennessee Valley Authority,

1101 Market Street, MR 3K-C, Chattanooga, Tennessee 37408; telephone 423-751-2193, or email *gsbrinkworth@tva.gov*.

**SUPPLEMENTARY INFORMATION:** TVA is an agency and instrumentality of the United States, established by an act of Congress in 1933, to foster the social and economic welfare of the people of the Tennessee Valley region and to promote the proper use and conservation of the region's natural resources. One component of this mission is the generation, transmission, and sale of reliable and affordable electric energy. TVA operates the largest public power system in the nation, providing electricity to about 9 million people in an 80,000-square mile area comprised of most of Tennessee and parts of Virginia, North Carolina, Georgia, Alabama, Mississippi, and Kentucky. It provides wholesale power to 155 independent power distributors and 59 directly served large industrial and federal customers. The TVA Act requires the TVA power system to be self-supporting and operating on a nonprofit basis and directs TVA to sell power at rates as low as are feasible.

Dependable generating capability on the TVA power system is about 37,200 megawatts (MW). TVA generates most of this power with 3 nuclear plants, 10 coal-fired plants, 9 combustion-turbine plants, 6 combined cycle plants, 29 hydroelectric plants, a pumped-storage facility, and several small renewable facilities. These facilities generated 142.2 billion kilowatt-hours in fiscal year 2014. The major sources for this power were coal (40 percent), nuclear (33 percent), natural gas (13 percent), and hydroelectric (10 percent). Other sources comprised less than 1 percent of TVA generation. Total power delivered to customers in fiscal year 2014 was 161 gigawatt-hours (GWh). A portion of this delivered power was provided through long-term power purchase agreements.

The recently completed IRP updates TVA's 2011 IRP. Consistent with Section 113 of the Energy Policy Act of 1992, codified within the TVA Act, TVA employed a least-cost system planning process in developing the IRP. This process took into account the demand for electricity, energy resource diversity, reliability, costs, risks, environmental impacts, and the unique attributes of different energy resources.

**Future Demand for Energy**

TVA uses state-of-the-art energy forecasting models to predict future demands on its system. Because of the uncertainty in predicting future demands, TVA developed high, medium, and low forecasts for both

peak load (in MW) and annual net system energy (in GWh) through 2033. Peak load is predicted to grow at average annual rates of 1.1 percent in the medium-growth Current Outlook Scenario, 0.3 percent in the low-growth forecast, and 1.3 percent in the high-growth forecast. Net system energy is predicted to grow at an average annual rate of 1.0 percent in the medium-growth forecast, remain flat in the low-growth forecast, and grow at an average annual rate of 1.1 percent in the high-growth forecast.

Based on these load growth forecasts, TVA's current firm capacity (TVA generation, energy efficiency and demand response measures, and power purchase agreements), and including a 15 percent planning reserve margin, TVA would need additional energy resources in the future. The medium-growth case needs are 2,500 MW of additional capacity and 14,000 GWh of additional energy by 2020, growing to 11,600 MW and 51,000 GWh by 2033.

#### Alternatives Considered

Six alternative energy resource strategies were evaluated in the Draft SEIS and IRP. These resource planning strategies were identified as potential alternative means of serving future electrical energy demands on the TVA system while meeting least-cost system planning requirements. These alternative strategies are:

*Baseline Case (No Action Alternative):* The continued implementation of the 2011 IRP as modified by subsequent decisions by the TVA Board of Directors.

*Strategy A—The Reference Plan:* This strategy is similar to the Baseline Case but treats energy efficiency and renewable energy resources as selectable resources instead of defined inputs.

*Strategy B—Meet an Emission Target:* Resources are selected under this strategy to create a lower emitting carbon dioxide (CO<sub>2</sub>) profile by reducing system-wide direct emissions of CO<sub>2</sub> by 50 percent (to 557 lbs/megawatt-hour) by 2033 and by 80 percent by 2050 from 2005. The targeted CO<sub>2</sub> rate is measured at a system-wide level and thus differs from the state-by-state and technology-specific baselines in the recently issued Clean Power Plan.

*Strategy C—Focus on Long-Term, Market-Supplied Resources:* Under this strategy, TVA would minimize capital investments in owned energy resources by meeting most capacity needs through power purchase agreements.

*Strategy D—Maximize Energy Efficiency:* Energy efficiency would be given priority in meeting capacity needs

with other resources selected to serve the remaining need.

*Strategy E—Maximize Renewables:* Renewable energy resources (hydroelectric, biomass, wind and solar) are emphasized by setting near-term and long-term renewable energy targets.

The alternative strategies were analyzed in the context of five scenarios or future "worlds" that were determined to be reasonably possible to occur. The scenarios were TVA's current outlook, a stagnant economy, a growth economy, a de-carbonized future, and a distributed energy marketplace. Each scenario is a set of uncertainties relevant to power system planning that include plausible future economic, financial, regulatory and legislative conditions, as well as social trends and adoption of technological innovations. Potential 20-year capacity expansion plans or resource portfolios were developed for each combination of alternative strategy and scenario using a capacity planning model. The model built each portfolio from a range of potential energy resource options that included TVA's existing energy resources and new coal, nuclear, natural gas, hydroelectric, wind, solar, and biomass generation, energy storage, and energy efficiency and demand response resources. Each portfolio was optimized for the lowest Present Value of Revenue Requirements while meeting energy balance, reserve, operational, and other requirements. The portfolios were then evaluated using an hourly production costing program to determine detailed revenue requirements and near- and long-term system average costs. Recognizing the uncertainty in long-range planning studies, extensive stochastic analyses were also conducted to identify risk exposure within each scenario. Additional metrics developed to rank the portfolios included financial risk, CO<sub>2</sub> emissions, water consumption, coal waste generation and changes in regional personal income. These metrics were used to compare the alternative strategies and their associated portfolios.

Strategies A–C had similar scores for most metrics and the scores for Strategies A and B were almost identical and for some metrics slightly better than Strategy C. Strategy E, with the greatest emphasis on renewable energy resources, scored the best on the three environmental metrics of CO<sub>2</sub> emissions, water consumption, and coal waste production. Strategy D had somewhat greater environmental impacts than Strategy E, and Strategies A–C had the greatest and similar environmental impacts. To better inform the development of the preferred

alternative, TVA conducted additional sensitivity analyses that varied key resource assumptions involving nuclear additions, energy efficiency, renewable resources, fundamental drivers such as load growth and fuel pricing, and the effect of forcing the model to consider resource types and/or amounts that it otherwise would not. The results of these analyses supported the energy resource ranges identified in the initial portfolios.

TVA then developed a preferred alternative, the Target Power Supply Mix, based on guideline ranges for key energy resources. In developing it, TVA took into account its least-cost planning requirement and customer priorities of power cost and reliability, as well as other comments it received during the public comment on the Draft IRP and SEIS. The Target Power Supply Mix establishes ranges, in MW, for coal plant retirements and additions of nuclear, hydroelectric, demand response, energy efficiency, solar, wind, and natural gas capacity. The recommended ranges are based on Strategies A–C and the Current Outlook Scenario, expressed over the 20-year planning period with more specific direction over the first 10-year period. The Target Power Supply Mix also includes broader ranges resulting from the sensitivity analyses. Shifts in resource additions within the ranges would be based on changes in the load forecast, the price of natural gas and other commodities, the price and performance of energy efficiency and renewable resources, and impacts from regulatory policy or breakthrough technologies.

#### Public Involvement

TVA published a notice of intent to prepare the IRP SEIS in the **Federal Register** on October 31, 2013. TVA then actively engaged the public through public scoping and public briefings during the development of the IRP and SEIS. TVA also established an IRP Working Group to more actively engage stakeholders. Group members included representatives of local power companies (distributors of TVA power), state agencies, direct-served customers, academia, and energy and environmental non-governmental organizations. Members of the group met frequently with IRP staff to review and provide input during the development of the plan.

The Notice of Availability of the Draft IRP and SEIS was published in the **Federal Register** by the U.S. Environmental Protection Agency (USEPA) on March 13, 2015. TVA accepted comments on the draft plan and SEIS until April 27, 2015. During

the comment period, TVA held seven public meetings to describe the project and accept comments. TVA received about 200 comments signed by more than 2,400 individuals. After considering and responding to all substantive comments, further evaluating the alternative strategies, and developing the Target Power Supply Mix, TVA issued the Final IRP and SEIS. The NOA for the Final IRP and SEIS was published in the **Federal Register** on July 17, 2015.

#### Environmentally Preferred Alternative

All of the alternative strategies, as well as the Target Power Supply Mix, have several common features that affect their anticipated environmental impacts. The only new baseload generation added is the extended power uprate of three nuclear units, a component of all alternative strategies. All result in decreases in coal-fired generation and increases in the reliance on energy efficiency and renewable resources. All also add varying amounts of new natural gas-fueled generation to meet peak loads. Emissions of air pollutants and CO<sub>2</sub>, and generation of coal waste would decrease significantly under all alternative strategies, including the Target Power Supply Mix. Water-related impacts would also decrease, although by smaller proportions. The major differences in the alternative strategies that affect their environmental impacts are in the expansion of energy efficiency and natural gas and renewable resources.

Strategies A–C and the Target Power Supply Mix have similar environmental impacts and their impacts to most environmental resources are greater than those of Strategies D and E. Because of its greater reliance on generation by fossil fuels, Strategy D has somewhat greater impacts to most environmental resources than Strategy E. Strategy E has the greatest reliance on renewable energy resources, which, particularly for utility-scale solar generation, have large land requirements. Strategy E would therefore directly affect the largest land area, almost twice that of the other alternative strategies and the Target Power Supply Mix. Relative to other types of generation, impacts of solar facilities on land resources are low. Overall, Strategy E is considered the environmentally preferred alternative.

#### Decision

On August 21, 2015, the TVA Board of Directors approved the preferred alternative, the Target Power Supply Mix. The Board also directed staff to monitor future developments to help

determine when deviations from the recommended resource ranges should be made and to initiate an update to the IRP no later than 2020 and earlier if future developments make this appropriate.

#### Mitigation Measures

The reduction of environmental impacts was an important goal in TVA's integrated resource planning process and all of the alternatives assessed by TVA do that. Because this is a programmatic review, measures to reduce potential environmental impacts on a site-specific level were not identified. As TVA deploys specific energy resources, it will review and take measures to reduce their potential environmental impacts as appropriate. TVA's siting process for generation and transmission facilities, as well as processes for modifying these facilities, are designed to avoid and/or minimize potential adverse environmental impacts. Potential impacts will also be reduced through pollution prevention measures and environmental controls such as air pollution control systems, wastewater treatment systems, and thermal generating plant cooling systems. Other potentially adverse unavoidable impacts will be mitigated by measures such as compensatory wetlands mitigation, payments to in-lieu stream mitigation programs and related conservation initiatives, enhanced management of other properties, documentation and recovery of cultural resources, and infrastructure improvement assistance to local communities.

Dated: October 16, 2015.

**Van M. Wardlaw,**

*Executive Vice President and Chief External Relations Officer.*

[FR Doc. 2015–27129 Filed 10–23–15; 8:45 am]

**BILLING CODE 8120–08–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Public Notice for Waiver of Aeronautical Land-Use Assurance; Airport Property at Palmer Municipal Airport, Palmer, Alaska

**AGENCY:** Federal Aviation Administration, Department of Transportation.

**ACTION:** Notice of intent of waiver with respect to land.

**SUMMARY:** Notice is hereby given per 49 U.S.C. 47107(h)(1)(A) that the Federal Aviation Administration (FAA) is considering a proposal to change

approximately 9.1 acres of airport land from aeronautical use to non-aeronautical use and to authorize the sale of this airport property.

As described in the 2011 approved Airport Layout Plan, the 9.1 acres of airport land are composed of Tract C Lots LL 2 and LL 3, and Tract D Lot LL 1C. Presently these properties are occupied as follows: LL 2 Mat-Su Borough Nutrition Center, LL 3 Baseball Fields, and LL 1C City Water Well.

**DATES:** Comments must be received on or before November 25, 2015.

**ADDRESSES:** Send comments on this document to Mike Edelman, Aviation Planner, Federal Aviation Administration, Alaskan Region Airports Division, 222 W. 7th Avenue, #14, Anchorage, AK 99513–7587. In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: City of Palmer Alaska POC Jeffrey Combs Airport Superintendent (907) 761–1334 [JJCOMBS@palmerak.org](mailto:JJCOMBS@palmerak.org) 231 West Evergreen, Palmer AK 99645.

**FOR FURTHER INFORMATION CONTACT:** Mr. Michael Edelman, Federal Aviation Administration, Alaskan Region Airports Division, 222 W. 7th Avenue, #14, Anchorage, AK 99513–7587, telephone 907–271–5026, email [mike.edelman@faa.gov](mailto:mike.edelman@faa.gov) or Jeffrey Combs Airport Superintendent (907) 761–1334, [JJCOMBS@palmerak.org](mailto:JJCOMBS@palmerak.org), 231 West Evergreen, Palmer AK 99645.

Issued in Anchorage, Alaska, on October 20, 2015.

**Byron Huffman,**

*Division Manager, FAA, Alaskan Region.*

[FR Doc. 2015–27185 Filed 10–23–15; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Aviation Medical Examiner Program

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

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on August

12, 2015. This collection is necessary in order to determine applicants' qualifications for certification as Aviation Medical Examiners (AMEs).

**DATES:** Written comments should be submitted by November 25, 2015.

**ADDRESSES:** Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov), or faxed to (202) 395-6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

*Public Comments Invited:* You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

**FOR FURTHER INFORMATION CONTACT:** Ronda Thompson at (202) 267-1416, or by email at: [Ronda.Thompson@faa.gov](mailto:Ronda.Thompson@faa.gov).

**SUPPLEMENTARY INFORMATION:**

*OMB Control Number:* 2120-0604.

*Title:* Aviation Medical Examiner Program.

*Form Numbers:* FAA Form 8520-2.

*Type of Review:* Renewal of an information collection.

*Background:* The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on August 12, 2015 (80 FR 48391). 14 CFR part 183 describes the requirements for delegating to private physicians the authority to conduct physical examinations on persons wishing to apply for their airmen medical certificate. This collection of information is for the purpose of obtaining essential information concerning the applicants' professional and personal qualifications. The FAA uses the information to screen and select the designees who serve as aviation medical examiners.

*Respondents:* Approximately 450 applicants annually.

*Frequency:* Information is collected on occasion.

*Estimated Average Burden per Response:* 30 minutes.

*Estimated Total Annual Burden:* 225 hours.

Issued in Washington, DC, on October 14, 2015.

**Ronda Thompson,**

*FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP-110.*

[FR Doc. 2015-27171 Filed 10-23-15; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Motor Carrier Safety Administration**

**Docket No. FMCSA-2012-0081]**

**Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillators**

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of denials of exemption applications.

**SUMMARY:** FMCSA announces its decision to deny applications from 14 of 15 individuals seeking exemptions from the Federal cardiovascular standard applicable to interstate truck and bus drivers and the reasons for the denials. The Agency reviewed the medical information of each of the individuals who applied for an implantable cardioverter defibrillator (ICD) exemption. Because the medical information received from the cardiologist concerning one individual indicates the ICD has been disabled due to improvement of his heart function, the exemption is no longer needed to operate commercial motor vehicles (CMVs) in interstate commerce. Based on a review of the applications and following an opportunity for public comment, FMCSA has concluded that the remaining 14 individuals in the notice did not demonstrate they could achieve a level of safety that is equivalent to, or greater than, the level of safety that would be obtained by complying with the regulation.

**DATES:** Denial letters were sent to each of the individuals listed in this notice on July 24, 2015.

**FOR FURTHER INFORMATION CONTACT:** Ms. Christine A. Hydock, Chief Medical Programs Division, 202-366-4001, U.S. Department of Transportation, FMCSA, 1200 New Jersey Avenue SE., Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

**Background**

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." FMCSA can renew exemptions at the end of each 2-year period.

On April 21, 2015, FMCSA published for public notice and comment, FMCSA 2012-0081 listing 15 individuals seeking exemptions for ICDs. Accordingly, the Agency has evaluated each applicant's request to determine whether granting an exemption will achieve the required level of safety mandated by statute.

**Evaluation Criteria—Cardiovascular Medical Standard and Advisory Criteria**

The individuals included in this notice have requested an exemption from the provisions of 49 CFR 391.41(b)(4), which applies to drivers who operate CMVs in interstate commerce, as defined in 49 CFR 390.5. Section 391.41(b)(4) states that:

" . . . a person is physically qualified to drive a commercial motor vehicle if that person has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope (temporary loss of consciousness due to a sudden decline in blood flow to the brain), dyspnea (shortness of breath), collapse, or congestive cardiac failure."

The FMCSA provides medical advisory criteria as recommendations for use by medical examiners in determining whether drivers with certain medical conditions, procedures, and/or treatments should be certified to operate CMVs in interstate commerce in accordance with the various physical qualification standards in 49 CFR part 391, subpart E. The advisory criteria are currently set out as part of the medical examination report published with 49 CFR 391.43. The advisory criteria for section 391.41(b)(4) provide that:

The term "has no current clinical diagnosis of" is specifically designed to encompass: "a clinical diagnosis of" (1) a current cardiovascular condition, or (2) a cardiovascular condition which has not fully stabilized regardless of the time limit. The term "known to be accompanied by" is designed to include a clinical diagnosis of a cardiovascular disease (1) which is accompanied by symptoms of syncope, dyspnea, collapse or congestive cardiac failure; and/or (2) which is likely to cause

syncope, dyspnea, collapse, or congestive cardiac failure.

It is the intent of the FMCSRs to render unqualified, a driver who has a current cardiovascular disease which is accompanied by and/or likely to cause symptoms of syncope, dyspnea, collapse, or congestive cardiac failure. However, the subjective decision of whether the nature and severity of an individual's condition will likely cause symptoms of cardiovascular insufficiency is on an individual basis and qualification rests with the medical examiner and the motor carrier.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope (a transient loss of consciousness) or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. See the Evidence Report on Cardiovascular Disease and Commercial Motor vehicle Driver Safety, April 2007.<sup>1</sup> A focused research report on Implantable Cardioverter Defibrillators and the Impact of a Shock on a Patient When Deployed completed for the FMCSA December 2014 indicates that the available scientific data on persons with ICDs and CMV driving does not support that persons with ICDs who operate CMVs are able to meet an equal or greater level of safety and upholds the findings of the April 2007 report.

#### Discussion of Public Comments

On April 21, 2015, FMCSA published in a **Federal Register** Notice, the names of 15 individuals requesting ICD exemption and requested public comment. The public comment period closed on May 21, 2015. A total of 29 commenters responded to the notice. The majority of commenters were in favor of the applicants continuing to drive CMV's with ICD's. Commenters believed that the individuals seeking exemptions were responsible drivers who had safe driving histories and were compliant with their medical treatment programs. One anonymous commenter encouraged the FMCSA not to grant these individuals exemptions due to concerns of the risks of the underlying medical conditions in combination with operating a commercial motor vehicle.

#### FMCSA's Response

FMCSA acknowledges the commenters' reports of medical compliance and safe driving histories of the applicants. However, based on the available medical literature and data, FMCSA believes that drivers with an

ICD are at risk for incapacitation if the device discharges in response to cardiovascular symptoms. This risk is combined with the risks associated with the underlying cardiovascular condition for which the ICD has been implanted as a primary or secondary preventive measure.

Mr. Leslie Mitchell no longer has a functioning ICD and may operate CMVs in interstate commerce based on the decision of the medical examiner. Mr. Mitchell has a pacemaker/ICD but the ICD portion was disabled because his cardiologist determined he no longer needs tachycardia therapy. Therefore, if a medical examiner determines that he meets the cardiovascular standard and all other physical qualification standards for operating a commercial motor vehicle in interstate commerce, he may be issued a medical certificate.

#### Conclusion

FMCSA evaluated the remaining 14 of 15 individual exemption requests on their merits, available data from Evidence Reports and Medical Expert Panel opinions on ICDs and commercial motor vehicle driving, and the public comments received. The Agency has determined that the available medical literature and data does not support a conclusion that granting these exemptions would achieve a level of safety equivalent to or greater than, the level of safety maintained without the exemptions. Each applicant has, prior to this notice, received a letter of final disposition on his/her exemption request. Those decision letters fully outlined the basis for the denial and constitute final Agency action. The list published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

The following 14 applicants are denied exemptions from the cardiovascular standard concerning ICDs.

Craig Bohms  
James Dean  
Terry Goodhile  
David Allan Jensen  
Michael Politz  
Charles Rhodes  
Mark Steiner  
Daniel Donahue  
Bernard Fritzson  
Ronald Heinlein  
Douglas Lopez  
Mark Register  
Stephen Watts  
John Allen Weltz

Issued on: October 15, 2015.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2015-27210 Filed 10-23-15; 8:45 am]

**BILLING CODE 4910-EX-P**

## DEPARTMENT OF TRANSPORTATION

### Pipeline and Hazardous Materials Safety Administration

[Docket ID PHMSA-2014-0092]

#### Pipeline Safety: National Pipeline Mapping System; Extension of Comment Period and Notice of Operator Workshop

**AGENCY:** Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

**ACTION:** Notice and request for comments; extension of comment period and announcement of a National Pipeline Mapping System Operator Technical Workshop.

**SUMMARY:** PHMSA is sponsoring a one-day National Pipeline Mapping System (NPMS) operator technical workshop on November 18, 2015, at a Washington, DC area hotel. This notice also announces that the comment period for the 60-day information collection published on August 27, 2015, (80 FR 52084) is extended until November 25, 2015, in order to conduct this workshop that will provide PHMSA with important information as it prepares to improve the NPMS submission process to accept additional data.

**DATES:** The NPMS operator technical workshop will be held on November 18, 2015, at a Washington, DC-area hotel, from 8:00 a.m. to 5:00 p.m. The comment period for the 60-day information collection published on August 27, 2015 (80 FR 52084) is extended from October 26, 2015 to November 25, 2015.

**ADDRESSES:** The workshop location, and hotel information will be announced in PRIMIS at <https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=107> once the conference room space has been procured.

#### FOR FURTHER INFORMATION CONTACT:

Amy Nelson at 202-493-0591 or by email at [amy.nelson@dot.gov](mailto:amy.nelson@dot.gov).

**SUPPLEMENTARY INFORMATION:** The purpose of the workshop is to discuss and understand existing and future NPMS submission technical issues such as (1) the format in which operators are storing the data that is submitted to the NPMS, (2) how pipe segmentation for the submissions is determined, (3) how data is submitted in a linear referencing format, and (4) options Geographic Information Systems technicians have when an attribute includes the word "predominant" (*i.e.*, submitting actual data or rolling up data to create a "predominant" value). This workshop will not discuss any proposed new data

<sup>1</sup> Now available at [http://ntl.bts.gov/lib/30000/30100/30123/Final\\_CVD\\_Evidence\\_Report\\_v2.pdf](http://ntl.bts.gov/lib/30000/30100/30123/Final_CVD_Evidence_Report_v2.pdf).

elements (attributes) or operators' opinions on the new data elements (attributes). Because this workshop will rely heavily on dialogue between PHMSA staff and operators in a "whiteboard" environment, the workshop will not be webcast.

**Registration:** Members of the public may attend this public meeting for free. To help assure that adequate space is provided, all attendees are encouraged to register for the workshop at <https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=107>. Name badge pick up and on-site registration will be available starting at 7:30 a.m., eastern time on November 18, 2015, with the workshop taking place from 8:00 a.m. until approximately 5:00 p.m. eastern time. Refer to the meeting Web site for agenda and times at <https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=107>.

**Comments:** Members of the public may also submit written comments regarding the NPMS Information Collection until November 25, 2015. Comments should reference Docket ID PHMSA-2014-0092. Comments may be submitted in the following ways:

- **E-Gov Web site:** <http://www.regulations.gov>. This site allows the public to enter comments on any **Federal Register** notice issued by any agency. Follow the instructions for submitting comments.
- **Fax:** 1-202-493-2251.
- **Mail:** Docket Management System, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, Washington, DC 20590.
- **Hand Delivery:** DOT Docket Management System, Room W12-140, on the ground floor of the West Building, 1200 New Jersey Avenue SE., Washington, DC between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

**Instructions:** Identify the Docket ID at the beginning of your comments. If you submit your comments by mail, submit two copies. If you wish to receive confirmation that PHMSA has received your comments, include a self-addressed stamped postcard. Internet users may submit comments at <http://www.regulations.gov>.

**Note:** Comments will be posted without changes or edits to <http://www.regulations.gov> including any personal information provided.

**Privacy Act Statement:** Anyone may search the electronic form of all comments received for any of our dockets. You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477).

**Information on Services for Individuals with Disabilities:** For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, please contact Amy Nelson at (202) 493-0591 or by email at [amy.nelson@dot.gov](mailto:amy.nelson@dot.gov) by November 9, 2015.

Issued in Washington, DC, on October 20, 2015, under authority delegated in 49 CFR 1.97.

**Alan K. Mayberry,**  
Deputy Associate Administrator for Policy and Programs.

[FR Doc. 2015-27120 Filed 10-23-15; 8:45 am]

**BILLING CODE 4910-60-P**

## DEPARTMENT OF TRANSPORTATION

### Intelligent Transportation Systems Program Advisory Committee; Notice of Meeting

**AGENCY:** ITS Joint Program Office, Office of the Assistant Secretary for Research and Technology, U.S. Department of Transportation.

**ACTION:** Notice.

The Intelligent Transportation Systems (ITS) Program Advisory Committee (ITSPAC) will hold a teleconference on November 13, 2015, from 1:00 p.m. to 2:00 p.m. (EST).

The ITSPAC, established under section 5305 of Public Law 109-59, Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, August 10, 2005, and re-established under section 53003 of Public Law 112-141, Moving Ahead for Progress in the 21st Century, July 6, 2012, was created to advise the Secretary of Transportation on all matters relating to the study, development, and implementation of intelligent transportation systems. Through its sponsor, the ITS Joint Program Office (JPO), the ITSPAC makes recommendations to the Secretary regarding ITS Program needs, objectives, plans, approaches, content, and progress.

The following is a summary of the meeting tentative agenda: (1) Welcome, (2) Reflections on 2015 Advice Memorandum, (3) Planning for March 2016 Meeting, (4) Discussion of Topics for 2016 Advice Memorandum, (5) Summary and Adjourn.

The teleconference will be open to the public, but limited conference lines will be available on a first-come, first-served basis. Members of the public who wish to participate in the teleconference must submit a request to [ITSPAC@dot.gov](mailto:ITSPAC@dot.gov), not later than November 6, 2015. In

addition, for planning purposes, your request must indicate whether you wish to present oral statements during the teleconference.

Questions about the agenda or written comments may be submitted by U.S. Mail to: U.S. Department of Transportation, Office of the Assistant Secretary for Research and Technology, ITS Joint Program Office, Attention: Stephen Glasscock, 1200 New Jersey Avenue SE., HOIT, Washington, DC 20590 or faxed to (202) 493-2027. The ITS JPO requests that written comments be submitted not later than November 6, 2015.

Notice of this teleconference is provided in accordance with the Federal Advisory Committee Act and the General Services Administration regulations (41 CFR part 102-3) covering management of Federal advisory committees.

Issued in Washington, DC, on the 20 day of October 2015.

**Stephen Glasscock,**  
Designated Federal Official, ITS Joint Program Office.

[FR Doc. 2015-27075 Filed 10-23-15; 8:45 am]

**BILLING CODE 4910-22-P**

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

#### Sanctions Actions Pursuant to Executive Orders 13224

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Notice.

**SUMMARY:** The Treasury Department's Office of Foreign Assets Control (OFAC) is publishing the names of one individual whose property and interests in property is blocked pursuant to Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism."

**DATES:** OFAC's action described in this notice is effective on October 20, 2015.

**FOR FURTHER INFORMATION CONTACT:** Associate Director for Global Targeting, tel.: 202/622-2420, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622-2490, Assistant Director for Licensing, tel.: 202/622-2480, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622-2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

**SUPPLEMENTARY INFORMATION:**

### Electronic and Facsimile Availability

The SDN List and additional information concerning OFAC sanctions programs are available from OFAC's Web site ([www.treasury.gov/ofac](http://www.treasury.gov/ofac)). Certain general information pertaining to OFAC's sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622-0077.

### Notice of OFAC Actions

On October 20, 2015, OFAC blocked the property and interests in property of the following individual pursuant to E.O. 13224, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism":

AGHA, Torek (a.k.a. AGHA, Torak; a.k.a. AGHA, Toriq; a.k.a. HASHAN, Sayed Mohammad; a.k.a. SAYED, Toriq Agha), Pashtunabad, Quetta, Pakistan; DOB 01 Jan 1964 to 31 Dec 1966; alt. DOB 01 Jan 1961 to 31 Dec 1963; alt. DOB 1960; POB Kandahar Province, Afghanistan; alt. POB Pishin, Balochistan Province, Pakistan; Identification Number 5430312277059 (Pakistan); Haji (individual) [SDGT] (Linked To: TALIBAN).

Dated: October 20, 2015.

**John E. Smith,**

*Acting Director, Office of Foreign Assets Control.*

[FR Doc. 2015-27116 Filed 10-23-15; 8:45 am]

**BILLING CODE 4810-AL-P**

## DEPARTMENT OF THE TREASURY

### Debt Management Advisory Committee Meeting

Notice is hereby given, pursuant to 5 U.S.C. App. 2, 10(a)(2), that a meeting will be held at the Hay-Adams Hotel, 16th Street and Pennsylvania Avenue NW., Washington, DC, on November 3, 2015 at 11:30 a.m. of the following debt management advisory committee:

Treasury Borrowing Advisory Committee of The Securities Industry and Financial Markets Association.

The agenda for the meeting provides for a charge by the Secretary of the Treasury or his designate that the Committee discuss particular issues and conduct a working session. Following the working session, the Committee will present a written report of its recommendations. The meeting will be closed to the public, pursuant to 5 U.S.C. App. 2, 10(d) and Public Law 103-202, § 202(c)(1)(B) (31 U.S.C. 3121 note).

This notice shall constitute my determination, pursuant to the authority placed in heads of agencies by 5 U.S.C. App. 2, 10(d) and vested in me by

Treasury Department Order No. 101-05, that the meeting will consist of discussions and debates of the issues presented to the Committee by the Secretary of the Treasury and the making of recommendations of the Committee to the Secretary, pursuant to Public Law 103-202, § 202(c)(1)(B).

Thus, this information is exempt from disclosure under that provision and 5 U.S.C. 552b(c)(3)(B). In addition, the meeting is concerned with information that is exempt from disclosure under 5 U.S.C. 552b(c)(9)(A). The public interest requires that such meetings be closed to the public because the Treasury Department requires frank and full advice from representatives of the financial community prior to making its final decisions on major financing operations. Historically, this advice has been offered by debt management advisory committees established by the several major segments of the financial community. When so utilized, such a committee is recognized to be an advisory committee under 5 U.S.C. App. 2, 3.

Although the Treasury's final announcement of financing plans may not reflect the recommendations provided in reports of the Committee, premature disclosure of the Committee's deliberations and reports would be likely to lead to significant financial speculation in the securities market. Thus, this meeting falls within the exemption covered by 5 U.S.C. 552b(c)(9)(A).

Treasury staff will provide a technical briefing to the press on the day before the Committee meeting, following the release of a statement of economic conditions and financing estimates. This briefing will give the press an opportunity to ask questions about financing projections. The day after the Committee meeting, Treasury will release the minutes of the meeting, any charts that were discussed at the meeting, and the Committee's report to the Secretary.

The Office of Debt Management is responsible for maintaining records of debt management advisory committee meetings and for providing annual reports setting forth a summary of Committee activities and such other matters as may be informative to the public consistent with the policy of 5 U.S.C. 552(b). The Designated Federal Officer or other responsible agency official who may be contacted for additional information is Fred Pietrangeli, Director for Office of Debt Management (202) 622-1876.

Dated: October 16, 2015.

**James Clark,**

*Deputy Assistant Secretary, (for Federal Finance).*

[FR Doc. 2015-26801 Filed 10-23-15; 8:45 am]

**BILLING CODE 4810-25-M**

## DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0017]

### Agency Information Collection (Supplement to VA Forms 21P-4706b, 21P-4706c and 21-4718a) Activity Under OMB Review

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before November 25, 2015.

**ADDRESSES:** Submit written comments on the collection of information through [www.Regulations.gov](http://www.Regulations.gov), or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). Please refer to "OMB Control No. 2900-0017" in any correspondence.

**FOR FURTHER INFORMATION CONTACT:** Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632-7492 or email [crystal.rennie@va.gov](mailto:crystal.rennie@va.gov). Please refer to "OMB Control No. 2900-0017."

#### SUPPLEMENTARY INFORMATION:

*Title:* Supplement to VA Forms 21P-4706b, 21P-4706c and 21-4718a  
*OMB Control Number:* 2900-0017.

*Type of Review:* Revision of a currently approved collection.

*Abstract:* VA maintains supervision of the distribution and use of VA benefits paid to fiduciaries on behalf of VA claimants who are incompetent, a minor, or under legal disability. The forms are used to verify beneficiaries'



deposit remaining at a financial institution against a fiduciary's accounting. The following forms will be used to ensure claimants' benefits payments are administered properly.

(a) VA Forms 21P-4706b and 4706c are used by estate to determine proper usage of benefits paid to fiduciaries. The 21P-4706b are both necessary to conform to requirement of various State courts.

(b) VA Form 21-4718a—Fiduciaries are required to obtain certifications that the balances remaining on deposit in financial institutions as shown on accountings are correct. Certifying official at a financial institution completing the form must affix the institution's official seal or stamp. The

data collected is used to appoint an appropriate fiduciary for a VA beneficiary and to prevent fiduciaries from supplying false certification, embezzling funds, and possibly prevent and/or identify fraud, waste and abuse of government funds paid to fiduciaries on behalf of VA beneficiaries.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 80 FR 46107 on August 3, 2015.

*Affected Public:* Individuals or households.

*Estimated Annual Burden:* 17,850.

(a) 21P-4706b: 12,600.

(b) 21P-4706c: 3,500.

(c) 21-4718a: 1,750.

*Estimated Average Burden per*

*Respondent:*

(a) 21P-4706b: 27 minutes.

(b) 21P-4706c: 30 minutes.

(c) 21-4718: 3 minutes.

*Frequency of Response:* Annually.

*Estimated Number of Respondents:* 35,000.

By direction of the Secretary.

**Kathleen M. Manwell,**

*Program Analyst, VA Privacy Service, Office of Privacy and Records Management, Department of Veterans Affairs.*

[FR Doc. 2015-27109 Filed 10-23-15; 8:45 am]

**BILLING CODE P**





# FEDERAL REGISTER

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Part II

## Environmental Protection Agency

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40 CFR Part 50, 51, 52, et al.

National Ambient Air Quality Standards for Ozone; Final Rule

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 50, 51, 52, 53, and 58

[EPA-HQ-OAR-2008-0699; FRL-9933-18-OAR]

RIN 2060-AP38

### National Ambient Air Quality Standards for Ozone

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** Based on its review of the air quality criteria for ozone (O<sub>3</sub>) and related photochemical oxidants and national ambient air quality standards (NAAQS) for O<sub>3</sub>, the Environmental Protection Agency (EPA) is revising the primary and secondary NAAQS for O<sub>3</sub> to provide requisite protection of public health and welfare, respectively. The EPA is revising the levels of both standards to 0.070 parts per million (ppm), and retaining their indicators (O<sub>3</sub>), forms (fourth-highest daily maximum, averaged across three consecutive years) and averaging times (eight hours). The EPA is making corresponding revisions in data handling conventions for O<sub>3</sub> and changes to the Air Quality Index (AQI); revising regulations for the prevention of significant deterioration (PSD) program to add a transition provision for certain applications; and establishing exceptional events schedules and providing information related to implementing the revised standards. The EPA is also revising the O<sub>3</sub> monitoring seasons, the Federal Reference Method (FRM) for monitoring O<sub>3</sub> in the ambient air, Federal Equivalent Method (FEM) analyzer performance requirements, and the Photochemical Assessment Monitoring Stations (PAMS) network. Along with exceptional events schedules related to implementing the revised O<sub>3</sub> standards, the EPA is applying this same schedule approach to other future new or revised NAAQS and removing obsolete regulatory language for expired exceptional events deadlines. The EPA is making minor changes to the procedures and time periods for evaluating potential FRMs and equivalent methods, including making the requirements for nitrogen dioxide (NO<sub>2</sub>) consistent with the requirements for O<sub>3</sub>, and removing an obsolete requirement for the annual submission of Product Manufacturing Checklists by manufacturers of FRMs and FEMs for monitors of fine and coarse particulate matter. For a more detailed summary, see the Executive Summary below.

**DATES:** The final rule is effective on December 28, 2015.

**ADDRESSES:** EPA has established a docket for this action (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), which has been incorporated by reference into the rulemaking docket. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) Web site. Although listed in the docket index, some information is not publicly available, e.g., confidential business information 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](http://www.regulations.gov) or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, 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](mailto:stone.susan@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### General Information

##### Availability of Related Information

A number of the documents that are relevant to this action are available through the EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Web site ([http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_index.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html)). These documents include the *Integrated Science Assessment for Ozone* (U.S. EPA, 2013), available at [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_2008\\_isa.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_2008_isa.html); the *Health Risk and Exposure Assessment* and the *Welfare Risk and Exposure Assessment for Ozone*, Final

Reports (HREA and WREA, respectively; U.S. EPA, 2014a, 2014b), available at [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_2008\\_rea.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_2008_rea.html); and the *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards* (PA; U.S. EPA, 2014c), available at [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_2008\\_pa.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_2008_pa.html). These and other related documents are also available for inspection and copying in the EPA docket identified above.

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#### References

#### Executive Summary

This section summarizes information about the purpose of this regulatory action, the major provisions of this action, and provisions related to implementation.

#### 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 make a final determination by October 1, 2015.

The EPA completed its most recent review of the NAAQS for O<sub>3</sub> in 2008. As a result of that review, EPA took four principal actions: (1) Revised the level of the 8-hour primary standard to 0.075 ppm; (2) expressed the standard to three decimal places; (3) revised the 8-hour secondary standard by making it identical to the revised primary standard; and (4) made conforming changes to the AQI.

In subsequent litigation, the U.S. Court of Appeals for the District of Columbia Circuit (DC Circuit) upheld the EPA's 2008 primary standard but remanded the 2008 secondary standard (*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 finding that the EPA's justification for setting the secondary standard identical to the revised 8-hour primary standard violated the CAA because the EPA had not adequately explained how that standard provided the required public welfare protection. In remanding the 2008 secondary standard, the court did not vacate it. The EPA has addressed the court's remand with this final action.

This final action reflects the Administrator's conclusions based on a review of the O<sub>3</sub> NAAQS that began in September 2008, and also concludes the EPA's reconsideration of the 2008 decision that it initiated in 2009 and subsequently consolidated with the current review. In conducting this review, the EPA has carefully evaluated the currently available scientific literature on the health and welfare effects of O<sub>3</sub>, focusing particularly on the new literature available since the conclusion of the previous review in 2008. 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 subject to 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 pursuant to the CAA and charged with providing advice to the Administrator.

The EPA proposed revisions to the primary and secondary O<sub>3</sub> NAAQS on December 17, 2014 (79 FR 75234), and provided a 3-month period for submission of comments from the public. In addition to written comments submitted to EPA, comments were also provided at public hearings held in Washington, DC, and Arlington, Texas, on January 29, 2015, and in Sacramento, California, on February 2, 2015. After consideration of public comments and the advice from the CASAC, the EPA has developed this final rulemaking, which is the final step in the review process.

In this rulemaking, the EPA is revising the suite of standards for O<sub>3</sub> to provide requisite protection of public health and welfare. In addition, the EPA is updating the AQI, and making changes in the data handling conventions and ambient air monitoring, reporting, and network

design requirements to correspond with the changes to the O<sub>3</sub> NAAQS.

#### *Summary of Major Provisions*

With regard to the primary standard, the EPA is revising the level of the standard to 0.070 ppm to provide increased public health protection against health effects associated with long- and short-term exposures. The EPA is retaining the indicator (O<sub>3</sub>), averaging time (8-hour) and form (annual fourth-highest daily maximum, averaged over 3 years) of the existing standard. This action provides increased protection for children, older adults, and people with asthma or other lung diseases, and other at-risk populations against an array of adverse health effects that include reduced lung function, increased respiratory symptoms and pulmonary inflammation; effects that contribute to emergency department visits or hospital admissions; and mortality.

The decisions on the adequacy of the current standard and the appropriate level for the revised standard are based on an integrative assessment of an extensive body of new scientific evidence, which substantially strengthens what was known about O<sub>3</sub>-related health effects in the last review. The revised standard also reflects consideration of a quantitative risk assessment that estimates public health risks likely to remain upon just meeting the current and various alternative standards. Based on this information, the Administrator concludes that the current primary O<sub>3</sub> standard is not requisite to protect public health with an adequate margin of safety, as required by the CAA, and that revision of the level to 0.070 ppm is warranted to provide the appropriate degree of increased public health protection for at-risk populations against an array of adverse health effects. In concluding that a revised primary standard set at a level of 0.070 ppm is requisite to protect public health with an adequate margin of safety, the Administrator relies on several key pieces of information, including: (a) A level of 0.070 ppm is well below the O<sub>3</sub> exposure concentration shown to cause the widest range of respiratory effects (*i.e.*, 0.080 ppm) and is below the lowest O<sub>3</sub> exposure concentration shown to cause the adverse combination of decreased lung function and increased respiratory symptoms (*i.e.*, 0.072 ppm); (b) a level of 0.070 ppm will eliminate, or nearly eliminate, repeated occurrence of these O<sub>3</sub> exposure concentrations (this is important because the potential for adverse effects increases with frequency of occurrence); (c) a level of 0.070 ppm

will protect the large majority of the population, including children and people with asthma, from lower exposure concentrations, which can cause lung function decrements and airway inflammation in some people (*i.e.*, 0.060 ppm); and (d) a level of 0.070 ppm will result in important reductions in the risk of O<sub>3</sub>-induced lung function decrements as well as the risk of O<sub>3</sub>-associated hospital admissions, emergency department visits, and mortality. In addition, the revised level of the primary standard is within the range that CASAC advised the Agency to consider.

The EPA is also revising the level of the secondary standard to 0.070 ppm to provide increased protection against vegetation-related effects on public welfare. The EPA is retaining the indicator (O<sub>3</sub>), averaging time (8-hour) and form (annual fourth-highest daily maximum, averaged over 3 years) of the existing secondary standard. This action, reducing the level of the standard, provides increased protection for natural forests in Class I and other similarly protected areas against an array of vegetation-related effects of O<sub>3</sub>. The Administrator is making this decision based on judgments regarding the currently available welfare effects evidence, the appropriate degree of public welfare protection for the revised standard, and currently available air quality information on seasonal cumulative exposures that may be allowed by such a standard.

In making this decision on the secondary standard, the Administrator focuses on O<sub>3</sub> effects on tree seedling growth as a proxy for the full array of vegetation-related effects of O<sub>3</sub>, ranging from effects on sensitive species to broader ecosystem-level effects. Using this proxy in judging effects to public welfare, the Administrator has concluded that the requisite protection will be provided by a standard that generally limits cumulative seasonal exposures to 17 ppm-hours (ppm-hrs) or lower, in terms of a 3-year W126 index. Based on air quality analyses which indicate such control of cumulative seasonal exposures will be achieved with a standard set at a level of 0.070 ppm (and the same indicator, averaging time, and form as the current standard), the Administrator concludes that a standard revised in this way will provide the requisite protection. In addition to providing protection of natural forests from growth-related effects, the revised standard is also expected to provide increased protection from other effects of potential public welfare significance, including crop yield loss and visible foliar injury.

Thus, based on all of the information available in this review, the Administrator concludes that the current secondary O<sub>3</sub> standard is not requisite to protect public welfare as required by the CAA, and that this revision will provide appropriate protection against known or anticipated adverse effects to the public welfare.

#### *Provisions Related to Implementation*

As directed by the CAA, reducing pollution to meet NAAQS 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<sub>3</sub> standards more than three decades ago, and is evidenced by significantly lower O<sub>3</sub> levels throughout the country. To provide a foundation that helps air agencies build successful strategies for attaining new O<sub>3</sub> standards, the EPA will continue to move forward with federal regulatory programs, such as 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. Given the regional nature of O<sub>3</sub> air pollution, the EPA will continue to work with states to address interstate transport of O<sub>3</sub> and O<sub>3</sub> precursors. The EPA also intends to work closely with states to identify locations affected by high background concentrations on high O<sub>3</sub> days due to stratospheric intrusions of O<sub>3</sub>, wildfire O<sub>3</sub> plumes, or long-range transport of O<sub>3</sub> from sources outside the U.S. and ensure that the appropriate CAA regulatory mechanisms are employed. To this end, the EPA will be proposing revisions to the 2007 Exceptional Events Rule and related draft guidance addressing the effects of wildfires.

In addition to revising the primary and secondary standards, this action is changing the AQI to reflect the revisions to the primary standard and also making corresponding revisions in data handling conventions for O<sub>3</sub>, extending the O<sub>3</sub> monitoring season in 33 states, revising the requirements for the PAMS network, and revising regulations for the PSD permitting program to add a provision grandfathering certain pending permits from certain requirements with respect to the revised standards. The preamble also provides schedules and information related to implementing the revised standards.

The rule also contains revisions to the schedules associated with exceptional events demonstration submittals for the revised O<sub>3</sub> standards and other future revised NAAQS, and makes minor changes related to monitoring for other pollutants.

## I. Background

### A. 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.”<sup>1</sup> 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.”<sup>2</sup>

<sup>1</sup> 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).

<sup>2</sup> 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

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 *Mississippi v. EPA*, 744 F. 3d 1334, 1353 (D.C. Cir. 2013); *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980); *American Petroleum Institute v. Costle*, 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; *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)<sup>3</sup> 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; *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

as effects on economic values and on personal comfort and well-being.”

<sup>3</sup> As used here with regard to human populations, 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 lifestyle.

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 CASAC<sup>4</sup> has performed this independent review function.

### B. Related Control Programs

States are primarily responsible for ensuring attainment and maintenance of NAAQS once the EPA has established them. The EPA performs an oversight function, and as necessary takes actions to ensure CAA objectives are achieved. Under section 110 of the CAA, and related provisions, states 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 relevant pollutants. The states, in conjunction with the EPA, also administer the PSD program (CAA sections 160 to 169) which is a pre-construction permit program designed to prevent significant deterioration in air quality. In addition, federal programs provide for nationwide reductions in emissions of O<sub>3</sub> precursors and other air pollutants through new source performance standards for stationary sources under section 111 of the CAA and the federal motor vehicle and motor vehicle fuel control program under title II of the CAA (sections 202

<sup>4</sup> Lists of CASAC members and of members of the CASAC Ozone Review Panel are accessible from: <http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC>.

to 250), which involves controls for emissions from mobile sources and controls for the fuels used by these sources. For some stationary sources, the national emissions standards for hazardous air pollutants under section 112 of the CAA may provide ancillary reductions in O<sub>3</sub> 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 are met. One of the first steps, known as the initial area designations, involves identifying areas of the country that are not meeting the new or revised NAAQS along with the nearby areas that contain emissions sources that contribute to the areas not meeting the NAAQS. For areas designated "nonattainment," the responsible states are required to develop SIPs to attain the standards. In developing their attainment plans, states 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<sub>3</sub> precursors are in place today or are expected to be in place by the time revised SIPs will be due. Examples of such rules include the Nitrogen Oxides (NO<sub>x</sub>) SIP Call and Cross-State Air Pollution Rule (CSAPR),<sup>5</sup> regulations controlling on-road and non-road engines and fuels, hazardous air pollutant rules for utility and industrial boilers, and various other programs already adopted by states to reduce emissions from key emissions sources. States will then evaluate the level of additional emission reductions needed for each nonattainment area to attain the O<sub>3</sub> standards "as expeditiously as practicable," and adopt new state regulations as appropriate. Section VIII of this preamble includes additional discussion of designation and implementation issues associated with the revised O<sub>3</sub> NAAQS.

### C. Review of Air Quality Criteria and Standards for O<sub>3</sub>

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 0.08 ppm,<sup>6</sup> as a 1-hour average of 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* (AQCD; U.S. DHEW, 1970). The EPA initiated the first periodic review of the NAAQS for photochemical oxidants in 1977. Based on the 1978 AQCD (U.S. EPA, 1978), the EPA published proposed revisions to the original NAAQS in 1978 (43 FR 26962, June 22, 1978) and final revisions in 1979 (44 FR 8202, February 8, 1979). At that time, the EPA revised the level of the primary and secondary standards from 0.08 to 0.12 ppm and changed the indicator from photochemical oxidants to O<sub>3</sub>, 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 EPA's 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<sub>3</sub> 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 AQCD (47 FR 11561; March 17, 1982), and, in 1983, the EPA initiated the second periodic review of the O<sub>3</sub> NAAQS (48 FR 38009; August 22, 1983). The EPA subsequently published the 1986 AQCD (U.S. EPA, 1986) and the 1989 Staff Paper (U.S.

EPA, 1989). Following publication of the 1986 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<sub>3</sub> to warrant preparation of a Supplement (U.S. EPA, 1992). In August of 1992, under the terms of a court order, the EPA proposed to retain the existing primary and secondary standards based on the health and welfare effects information contained in the 1986 AQCD and its 1992 Supplement (57 FR 35542, August 10, 1992). In March 1993, the EPA announced its decision to conclude this review by affirming its proposed decision to retain the standards, without revision (58 FR 13008, March 9, 1993).

In the 1992 notice of its proposed decision in that review, the EPA announced its intention to proceed as rapidly as possible with the next review of the air quality criteria and standards for O<sub>3</sub> in light of emerging evidence of health effects related to 6- to 8-hour O<sub>3</sub> exposures (57 FR 35542, August 10, 1992). The EPA subsequently published the AQCD and Staff Paper for the review (U.S. EPA, 1996a,b). In December 1996, the EPA proposed revisions to both the primary and secondary standards (61 FR 65716, December 13, 1996). With regard to the primary standard, the EPA proposed to replace the then-existing 1-hour primary standard with an 8-hour standard set at a level of 0.08 ppm (equivalent to 0.084 ppm based on the proposed data handling convention) as a 3-year average of the annual third-highest daily maximum 8-hour concentration. The EPA proposed to revise the secondary standard either by setting it identical to the proposed new primary standard or by setting it as a new seasonal standard using a cumulative form. The EPA completed this review in 1997 by setting the primary standard at a level of 0.08 ppm, based on the annual fourth-highest daily maximum 8-hour average concentration, averaged over three years, and setting the secondary standard identical to the revised primary standard (62 FR 38856, July 18, 1997). In reaching her decision on the primary standard, the Administrator identified several reasons supporting her decision to reject a potential alternate standard set at 0.07 ppm, including first the fact that no CASAC panel member supported a standard level lower than 0.08 ppm and her consideration of the scientific uncertainties with regard to the health effects evidence for exposure concentrations below 0.08 ppm. In addition to those reasons, the Administrator noted that a standard set

<sup>5</sup> The Cross-State Air Pollution Rule was upheld by the Supreme Court in *Environmental Protection Agency v. EME Homer City Generation, L.P.*, 134 S. Ct. 1584 (2014), and remanded to the D.C. Circuit for further proceedings. The D.C. Circuit issued its decision on remand from the Supreme Court on July 28, 2015, remanding CSAPR to EPA, without vacating the rule, for EPA to reconsider certain emission budgets for certain States (*EME Homer City Generation, L.P. v. Environmental Protection Agency*, No. 11–1302, 2015 WL 4528137 [D.C. Cir. July 28, 2015]).

<sup>6</sup> Although the level of the 2008 O<sub>3</sub> standards are specified in the units of ppm (*i.e.*, 0.075 ppm), O<sub>3</sub> concentrations are described using the units of parts per billion (ppb) in several sections of this notice (*i.e.*, sections II, III, IV and VI) for consistency with the common convention for information discussed in those sections. In ppb, 0.075 ppm is equivalent to 75.

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<sub>3</sub> 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<sub>3</sub> 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. vs. 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub>. 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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 the 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” (283 F. 3d at 378, internal citations omitted). The court also pointed to the significant weight that the EPA properly placed on the advice it received from CASAC (283 F. 3d at 379). In addition, the court noted that “although relative proximity to peak background O<sub>3</sub> concentrations did not, in itself, necessitate a level of 0.08 [ppm], the EPA could consider that factor when choosing among the three alternative levels” (283 F. 3d at 379).

Independently of the litigation, the EPA responded to the court's remand to consider the potential beneficial health effects of O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> NAAQS. The EPA also expressed the view that any plausible changes in UV-B radiation exposures from changes in patterns of ground-level O<sub>3</sub> concentrations would likely be very small from a public health perspective. In view of these findings, the EPA proposed to leave the 1997 primary standard unchanged (66 FR 57268, Nov. 14, 2001). After considering public comment on the proposed decision, the EPA published its final response to this remand in 2003, re-affirming the 8-hour primary standard set in 1997 (68 FR 614, January 6, 2003).

The EPA initiated the fourth periodic review of the air quality criteria and standards for O<sub>3</sub> with a call for information in September 2000 (65 FR 57810, September, 26, 2000). 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 nondiscretionary duty to complete review of the O<sub>3</sub> NAAQS within a

statutorily mandated deadline. In 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, July 11, 2007). The EPA proposed to revise the secondary standard either by setting it identical to the proposed new primary standard or by setting it as a new seasonal standard using a cumulative form. Documents supporting these proposed decisions included the 2006 AQCD (U.S. EPA, 2006a) and 2007 Staff Paper (U.S. EPA, 2007) and related technical support documents. The EPA completed the review in March 2008 by revising the level of the primary standard from 0.08 ppm to 0.075 ppm, and revising the secondary standard to be identical to the revised primary standard (73 FR 16436, March 27, 2008).

In May 2008, state, public health, environmental, and industry petitioners filed suit challenging the EPA's final decision on the 2008 O<sub>3</sub> standards. On September 16, 2009, the EPA announced its intention to reconsider the 2008 O<sub>3</sub> 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 2010, the EPA issued a notice of proposed rulemaking to reconsider the 2008 final decision (75 FR 2938, January 19, 2010). 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 revise the level of the primary standard from 0.075 ppm to a level within the range of 0.060 to 0.070 ppm, and to revise the secondary standard to one with a cumulative, seasonal form. At the EPA's request, the CASAC reviewed the proposed rule at a public teleconference on January 25, 2010 and provided additional advice in early 2011 (Samet, 2010, 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, 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<sub>3</sub> NAAQS required under CAA section 109 had already begun (as announced on September 29, 2008), the EPA decided to consolidate the



reconsideration with its statutorily required periodic review.<sup>7</sup>

In light of the 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<sub>3</sub> standard, but remanded the 2008 secondary standard to the EPA (*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" (*Mississippi v. EPA*, 744 F. 3d at 1345). The court also specifically endorsed the weight of evidence approach utilized by the EPA in its deliberations (*Mississippi v. EPA*, 744 F. 3d 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 (*Mississippi v. EPA*, 744 F. 3d 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<sub>3</sub> 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 (*Mississippi v. EPA*, 744 F. 3d at 1351–52).<sup>8</sup>

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

<sup>7</sup> This rulemaking concludes the reconsideration process. Under CAA section 109, the EPA is required to base its review of the NAAQS on the current air quality criteria, and thus the record and decision for this review also serve for the reconsideration.

<sup>8</sup> 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).

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 (*Mississippi v. EPA*, 744 F. 3d at 1351–52). Finally, the court rejected arguments that the EPA's decision was inconsistent with the CASAC's scientific recommendations because the CASAC had been insufficiently clear in its recommendations whether it was providing scientific or policy recommendations, and the EPA had reasonably addressed the CASAC's policy recommendations (*Mississippi v. EPA*, 744 F. 3d at 1357–58).

With respect to the secondary standard, the court held that the EPA's justification for setting the secondary standard identical to the revised 8-hour primary standard violated the CAA because the EPA had not adequately explained how that standard provided the required public welfare protection. The court thus remanded the secondary standard to the EPA (*Mississippi v. EPA*, 744 F. 3d 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<sub>3</sub> NAAQS. This review was formally initiated in 2008 with a call for information in the **Federal Register** (73 FR 56581, Sept. 29, 2008). On October 28–29, 2008, the EPA held a public workshop to discuss the policy-relevant science, which informed identification of key policy issues and questions to frame the review. Based in part on the workshop discussions, the EPA developed a draft Integrated Review Plan (IRP) outlining the schedule, process,<sup>9</sup> and key policy-relevant questions that would guide the evaluation of the air quality criteria for O<sub>3</sub> and the review of the primary and secondary O<sub>3</sub> NAAQS. A draft of the IRP was released for public review and comment in September 2009 and was the subject of a consultation with the CASAC on November 13, 2009 (74 FR 54562; October 22, 2009).<sup>10</sup> After considering the comments received from that consultation and from the public, the EPA completed and released the IRP for the review in 2011 (U.S. EPA, 2011a).

<sup>9</sup> As of this review, the document developed in NAAQS reviews to document the air quality criteria, previously the AQCD, is the ISA, and the document describing the OAQPS staff evaluation, previously the Staff Paper, is the PA. These documents are described in the IRP.

<sup>10</sup> See <http://yosemite.epa.gov/sab/sabproduct.nsf/WebProjectsByTopicCASAC!OpenView> for more information on CASAC activities related to the current O<sub>3</sub> NAAQS review.

In preparing the first draft ISA, the EPA's National Center for Environmental Assessment (NCEA) considered CASAC and public comments on the IRP, and also comments received from a workshop held on August 6, 2010, to review and discuss preliminary drafts of key ISA sections (75 FR 42085, July 20, 2010). In 2011, the first draft ISA was released for public comment and for review by CASAC at a public meeting on May 19–20, 2011 (U.S. EPA, 2011b; 76 FR 10893, February 28, 2011; 76 FR 23809, April 28, 2011). Based on CASAC and public comments, NCEA prepared a second draft ISA, which was released for public comment and CASAC review (U.S. EPA, 2011c; 76 FR 60820, September 30, 2011). The CASAC reviewed this draft at a January 9–10, 2012, public meeting (76 FR 236, December 8, 2011). Based on CASAC and public comments, NCEA prepared a third draft ISA (U.S. EPA, 2012; 77 FR 36534, June 19, 2012), which was reviewed at a CASAC meeting in September 2012. The EPA released the final ISA in February 2013 (U.S. EPA, 2013).

The EPA presented its plans for conducting Risk and Exposure Assessments (REAs) for health risk and exposure (HREA) and welfare risk and exposure (WREA) in two documents that outlined the scope and approaches for use in conducting quantitative assessments, as well as key issues to be addressed as part of the assessments (U.S. EPA, 2011d, e). 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). The EPA considered CASAC advice and public comments in further planning for the assessments, issuing a memo that described changes to elements of the REA plans and brief explanations regarding them (Samet, 2011; Wegman, 2012).

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; 77 FR 51798, August 27, 2012). The first draft PA was made available for CASAC review and public comment in August 2012 (77 FR 42495, July 19, 2012; 77 FR 51798, August 27, 2012).<sup>11</sup> The first

<sup>11</sup> The PA is prepared by the OAQPS staff. Formerly known as the Staff Paper, 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



draft REAs and PA were the focus of a CASAC public meeting in September 2012 (Frey and Samet, 2012a, 2012b). The second draft REAs and PA, prepared with consideration of CASAC advice and public comments, were made available for public comment and CASAC review in January 2014 (79 FR 4694, January 29, 2014). These documents were the focus of a CASAC public meeting on March 25–27, 2014 (Frey, 2014a; Frey, 2014b; Frey, 2014c). The final versions of these documents were developed with consideration of the comments and recommendations from CASAC, as well as comments from the public on the draft documents, and were released in August 2014 (U.S. EPA 2014a; U.S. EPA, 2014b; U.S. EPA, 2014c).

The proposed decision (henceforth “proposal”) on this review of the O<sub>3</sub> NAAQS was signed on November 25, 2014, and published in the **Federal Register** on December 17, 2014. The EPA held three public hearings to provide direct opportunity for oral testimony by the public on the proposal. The hearings were held on January 29, 2015, in Arlington, Texas, and Washington, DC, and on February 2, 2015, in Sacramento, California. At these public hearings, the EPA heard testimony from nearly 500 individuals representing themselves or specific interested organizations. Transcripts from these hearings and written testimony provided at the hearings are in the docket for this review. Additionally, approximately 430,000 written comments were received from various commenters during the public comment period on the proposal, approximately 428,000 as part of mass mail campaigns. Significant issues raised in the public comments are discussed in the preamble of this final action. A summary of all other significant comments, along with the EPA’s responses, can be found in a separate document (henceforth “Response to Comments”) in the docket for this review.

The schedule for completion of this review is governed by a court order resolving a lawsuit filed in January 2014 by a group of plaintiffs who alleged that the EPA had failed to perform its mandatory duty, under section 109(d)(1), to complete a review of the O<sub>3</sub> NAAQS within the period provided by statute. The court order that governs this review, entered by the court on April 30, 2014, provides that the EPA will sign for publication a notice of final

rulemaking concerning its review of the O<sub>3</sub> NAAQS no later than October 1, 2015.

As in prior NAAQS reviews, the EPA is basing its decision in this review on studies and related information included in the ISA, REAs and PA, which have undergone CASAC and public review. The studies assessed in the ISA and PA, and the integration of the scientific evidence presented in them, have undergone extensive critical review by the EPA, the CASAC, and the public. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by the EPA but also by the statutorily mandated independent advisory committee, as well as the public review that accompanies this process. Some commenters have referred to and discussed individual scientific studies on the health and welfare effects of O<sub>3</sub> that were not included in the ISA (USEPA, 2013) (“‘new’ studies”). In considering and responding to comments for which such “new” studies were cited in support, the EPA has provisionally considered the cited studies in the context of the findings of the ISA. The EPA’s provisional consideration of these studies did not and could not provide the kind of in-depth critical review described above.

The decision to rely on studies and related information included in the ISA, REAs and PA, which have undergone CASAC and public review, is consistent with the EPA’s practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and the EPA has consistently followed this approach. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. See 71 FR 61144, 61148 (October 17, 2006) (final decision on review of NAAQS for particulate matter) for a detailed discussion of this issue and the EPA’s past practice.

As discussed in the EPA’s 1993 decision not to revise the NAAQS for

O<sub>3</sub>, “new” studies may sometimes be of such significance that it is appropriate to delay a decision on revision of a NAAQS and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR at 13013–13014, March 9, 1993). In the present case, the EPA’s provisional consideration of “new” studies concludes that, taken in context, the “new” information and findings do not materially change any of the broad scientific conclusions regarding the health and welfare effects and exposure pathways of ambient O<sub>3</sub> made in the air quality criteria. For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking.

Accordingly, the EPA is basing the final decisions in this review on the studies and related information included in the O<sub>3</sub> air quality criteria that have undergone CASAC and public review. The EPA will consider the “new” studies for purposes of decision making in the next periodic review of the O<sub>3</sub> NAAQS, which the EPA expects to begin soon after the conclusion of this review and which will provide the opportunity to fully assess these studies through a more rigorous review process involving the EPA, CASAC, and the public. Further discussion of these “new” studies can be found in the Response to Comments document, which is in the docket for this rulemaking and also available on the web ([http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_index.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html)).

#### *D. 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) and NO<sub>x</sub>. Over longer time periods, methane (CH<sub>4</sub>) and carbon monoxide (CO) can also lead to O<sub>3</sub> formation at the global scale. The precursor emissions leading to O<sub>3</sub> 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<sub>3</sub> that is created naturally in the stratosphere can also contribute to O<sub>3</sub> levels near the surface. Once formed, O<sub>3</sub> near the surface can be transported by winds before eventually being removed from the atmosphere via chemical reactions or deposition to surfaces. In sum, O<sub>3</sub> concentrations are influenced by complex interactions between precursor emissions, meteorological conditions, and surface characteristics (U.S. EPA, 2014a).

and REAs, and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS.

In order to continuously assess O<sub>3</sub> air pollution levels, state and local environmental agencies operate O<sub>3</sub> monitors at various locations and subsequently submit the data to the EPA. At present, there are approximately 1,400 monitors across the U.S. reporting hourly O<sub>3</sub> averages during the times of the year when local O<sub>3</sub> pollution can be important (U.S. EPA, 2014c, Section 2.1). Much of this monitoring is focused on 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<sub>3</sub> can also be measured. Based on data from this national network, the EPA estimates that, in 2013, approximately 99 million Americans lived in counties where O<sub>3</sub> design values<sup>12</sup> were above the level of the existing health-based (primary) NAAQS of 0.075 ppm. High O<sub>3</sub> values can occur almost anywhere within the contiguous 48 states, although the poorest O<sub>3</sub> air quality in the U.S. is typically observed in California, Texas, and the Northeast Corridor, locations with some of the most densely populated areas in the country. From a temporal perspective, the highest daily peak O<sub>3</sub> 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<sub>3</sub> from upwind areas of regional production can occasionally result in high nighttime levels of O<sub>3</sub>, 2) high-elevation sites episodically influenced by stratospheric intrusions which can occur in other months, and 3) certain locations in the western U.S. where large quantities of O<sub>3</sub> 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<sub>3</sub> (U.S. EPA, 2014c, Section 2.3).

One of the challenging aspects of developing plans to address high O<sub>3</sub> concentrations is that the response of O<sub>3</sub> to precursor reductions is nonlinear. In particular, NO<sub>x</sub> emissions can lead to both increases and decreases of O<sub>3</sub>. The net impact of NO<sub>x</sub> emissions on O<sub>3</sub> concentrations depends on the local quantities of NO<sub>x</sub>, VOC, and sunlight which interact in a set of complex chemical reactions. In some areas, such as certain urban centers where NO<sub>x</sub>

emissions typically are high compared to local VOC emissions, NO<sub>x</sub> can suppress O<sub>3</sub> locally. This phenomenon is particularly pronounced under conditions associated with low O<sub>3</sub> concentrations (*i.e.*, during cool, cloudy weather and at night when photochemical activity is limited or nonexistent). However, while NO<sub>x</sub> emissions can initially suppress O<sub>3</sub> levels near the emission sources, these same NO<sub>x</sub> emissions ultimately react to form higher O<sub>3</sub> levels downwind when conditions are favorable. Photochemical model simulations suggest that, in general, reductions in NO<sub>x</sub> emissions in the U.S. will slightly increase O<sub>3</sub> concentrations on days with lower O<sub>3</sub> concentrations in close proximity to NO<sub>x</sub> sources (*e.g.*, in urban core areas), while at the same time decreasing the highest O<sub>3</sub> concentrations in downwind 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 metric, the W126 exposure index, is often used to assess impacts of O<sub>3</sub> exposure on ecosystems and vegetation. W126 is a cumulative seasonal aggregate of weighted hourly O<sub>3</sub> values observed between 8 a.m. and 8 p.m. As O<sub>3</sub> precursor emissions have decreased across the U.S., annual fourth-highest 8-hour O<sub>3</sub> maxima have concurrently shown a modest downward trend. The national average change in annual fourth-highest daily maximum 8-hour O<sub>3</sub> concentrations between 2000 and 2013 was an 18% decrease. The national average change in the annual W126 exposure index over the same period was a 52% decrease. Air quality model simulations estimate that O<sub>3</sub> air quality will continue to improve over the next decade as additional reductions in O<sub>3</sub> precursors from power plants, motor vehicles, and other sources are realized.

In addition to being affected by changing emissions, future O<sub>3</sub> concentrations may also be affected by climate change. Modeling studies in the EPA's Interim Assessment (U.S. EPA, 2009a) that are cited in support of the 2009 Endangerment Finding under CAA section 202(a) (74 FR 66496, Dec. 15, 2009) as well as a recent assessment of potential climate change impacts (Fann et al., 2015) project that climate change may lead to future increases in summer O<sub>3</sub> concentrations across the contiguous U.S.<sup>13</sup> While the projected impact is not

uniform, climate change has the potential to increase average summertime O<sub>3</sub> concentrations by as much as 1–5 ppb by 2030, if greenhouse gas emissions are not mitigated. Increases in temperature are expected to be the principal factor in driving any O<sub>3</sub> increases, although increases in stagnation frequency may also contribute (Jacob and Winner, 2009). If unchecked, climate change has the potential to offset some of the improvements in O<sub>3</sub> air quality, and therefore some of the improvements in public health, that are expected from reductions in emissions of O<sub>3</sub> precursors.

Another challenging aspect of this air quality issue is the impact from sources of O<sub>3</sub> and its precursors beyond those from domestic, anthropogenic sources. Modeling analyses indicate that nationally the majority of O<sub>3</sub> exceedances are predominantly caused by anthropogenic emissions from within the U.S. However, observational and modeling analyses have concluded that O<sub>3</sub> concentrations in some locations in the U.S. on some days can be substantially influenced by sources that cannot be addressed by domestic control measures. In particular, certain high-elevation sites in the western U.S. are impacted by a combination of non-U.S. sources like international transport, or natural sources such as stratospheric O<sub>3</sub>, and O<sub>3</sub> originating from wildfire emissions.<sup>14</sup> Ambient O<sub>3</sub> from these non-U.S. and natural sources is collectively referred to as background O<sub>3</sub>. See generally section 2.4 of the PA (U.S. EPA, 2014c). The analyses suggest that, at these locations, there can be episodic events with substantial background contributions where O<sub>3</sub> 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.

#### *E. Summary of Proposed Revisions to the O<sub>3</sub> Standards*

For reasons discussed in the proposal, the Administrator proposed to revise the

quality to climate change. A wide range of future climate scenarios and future years have been modeled and there can be variations in the expected response in U.S. O<sub>3</sub> by scenario and across models and years, within the overall signal of higher summer O<sub>3</sub> concentrations in a warmer climate.

<sup>14</sup> Without global greenhouse gas mitigation efforts, climate change is projected to dramatically increase the area burned by wildfires across most of the contiguous U.S., especially in the West (U.S. EPA, 2015 p. 72).

<sup>12</sup> A design value is a statistic that describes the air quality status of a given location relative to the level of the NAAQS.

<sup>13</sup> These modeling studies are based on coupled global climate and regional air quality models and are designed to assess the sensitivity of U.S. air

current primary and secondary standards for O<sub>3</sub>. With regard to the primary standard, the Administrator proposed to revise the level from 75 ppb to a level within a range from 65 to 70 ppb. The EPA proposed to revise the AQI for O<sub>3</sub>, consistent with revision to the primary standard.

With regard to the secondary standard, the Administrator proposed to revise the level of the current secondary standard to within the range of 0.065 to 0.070 ppm, which air quality analyses indicate would provide cumulative, seasonal air quality or exposure values, in terms of 3-year average W126 index values, at or below a range of 13–17 ppm-hours.

The EPA also proposed to make corresponding revisions in data handling conventions for O<sub>3</sub>; to revise regulations for the PSD permitting program to add a provision grandfathering certain pending permits from certain requirements with respect to the proposed revisions to the standards; 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<sub>3</sub> standards, the EPA also proposed to extend the new schedule approach to other future NAAQS revisions and to remove obsolete regulatory language associated with expired exceptional event deadlines for historical standards for both O<sub>3</sub> and other pollutants for which NAAQS have been established. The EPA also proposed to make minor changes to the procedures and time periods for evaluating potential FRMs and equivalent methods, including making the requirements for NO<sub>2</sub> consistent with the requirements for O<sub>3</sub>, and removing an obsolete requirement for the annual submission of documentation by manufacturers of certain particulate matter monitors.

#### *F. Organization and Approach to Decisions in This O<sub>3</sub> NAAQS Review*

This action presents the Administrator's final decisions in the current review of the primary and secondary O<sub>3</sub> standards. The final decisions addressing standards for O<sub>3</sub> are based on a thorough review in the ISA of scientific information on known and potential human health and welfare effects associated with exposure to O<sub>3</sub> at levels typically found in the ambient air. These final decisions also take into account the following: (1) Staff assessments in the PA of the most policy-relevant information in the ISA as well as a quantitative health and welfare exposure and risk assessments

based on that information; (2) CASAC advice and recommendations, as reflected in its letters to the Administrator and its discussions of drafts of the ISA, REAs, and PA at public meetings; (3) public comments received during the development of these documents, both in connection with CASAC meetings and separately; and (4) extensive public comments received on the proposed rulemaking.

The primary standard is addressed in section II. Corresponding changes to the AQI are addressed in section III. The secondary standard is addressed in section IV. Related data handling conventions and exceptional events are addressed in section V. Updates to the monitoring regulations are addressed in section VI. Implementation activities, including PSD-related actions, are addressed in sections VII and VIII. Section IX addresses applicable statutory and executive order reviews.

## **II. Rationale for Decision on the Primary Standard**

This section presents the Administrator's final decisions regarding the need to revise the existing primary O<sub>3</sub> standard and the appropriate revision to the level of that standard. Based on her consideration of the full body of health effects evidence and exposure/risk analyses, the Administrator concludes that the current primary standard for O<sub>3</sub> is not requisite to protect public health with an adequate margin of safety. In order to increase public health protection, she is revising the level of the primary standard to 70 ppb, in conjunction with retaining the current indicator, averaging time and form. The Administrator concludes that such a revised standard will be requisite to protect public health with an adequate margin of safety. As discussed more fully below, the rationale for these final decisions draws from the thorough review in the ISA (U.S. EPA, 2013) of the available scientific evidence, generally published through July 2011, on human health effects associated with the presence of O<sub>3</sub> in the ambient air. This rationale also takes into account: (1) Analyses of O<sub>3</sub> air quality, human exposures to O<sub>3</sub>, and O<sub>3</sub>-associated health risks, as presented and assessed in the HREA (U.S. EPA, 2014a); (2) the EPA staff assessment of the most policy-relevant scientific evidence and exposure/risk information in the PA (U.S. EPA, 2014c); (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; (4) public

input received during the development of these documents, either in connection with CASAC meetings or separately; and (5) public comments on the proposal notice.

Section II.A below summarizes the information presented in the proposal regarding O<sub>3</sub>-associated health effects, O<sub>3</sub> exposures, and O<sub>3</sub>-attributable health risks. Section II.B presents information related to the adequacy of the current primary O<sub>3</sub> standard, including a summary of the basis for the Administrator's proposed decision to revise the current standard, public comments received on the adequacy of the current standard, and the Administrator's final conclusions regarding the adequacy of the current standard. Section II.C presents information related to the elements of a revised primary O<sub>3</sub> standard, including information related to each of the major elements of the standard (*i.e.*, indicator, averaging time, form, level). Section II.D summarizes the Administrator's final decisions on the primary O<sub>3</sub> standard.

### *A. Introduction*

As discussed in section II.A of the proposal (79 FR 75243–75246, December 17, 2014), the EPA's approach to informing decisions on the primary O<sub>3</sub> standard in the current review builds upon the general approaches used in previous reviews and reflects the broader body of scientific evidence, updated exposure/risk information, and advances in O<sub>3</sub> air quality modeling now available. This approach 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<sub>3</sub> 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, 2013), exposure and risk analyses presented in the HREA (U.S. EPA, 2014a), evidence- and exposure-/risk-based considerations and conclusions presented in the PA (U.S. EPA, 2014c), advice and recommendations received from CASAC (Frey, 2014a, c), and public comments.

Section II.A.1 below summarizes the information presented in the proposal regarding O<sub>3</sub>-associated health effects. Section II.A.2 summarizes the information presented in the proposal regarding O<sub>3</sub> exposures and O<sub>3</sub>-attributable health risks.

## 1. Overview of Health Effects Evidence

The health effects of O<sub>3</sub> are described in detail in the ISA (U.S. EPA, 2013). Based on its assessment of the health effects evidence, the ISA determined that a “causal” relationship exists between short-term exposure to O<sub>3</sub> in ambient air and effects on the respiratory system<sup>15</sup> and that a “likely to be causal” relationship exists between long-term exposure to O<sub>3</sub> in ambient air and respiratory effects<sup>16</sup> (U.S. EPA, 2013, pp. 1–6 to 1–7). The ISA summarizes the longstanding body of evidence for O<sub>3</sub> respiratory effects as follows (U.S. EPA, 2013, p. 1–5):

The clearest evidence for health effects associated with exposure to O<sub>3</sub> is provided by studies of respiratory effects. Collectively, a very large amount of evidence spanning several decades supports a relationship between exposure to O<sub>3</sub> 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<sub>3</sub>, 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<sub>3</sub> 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, 2013, pp. 1–7 to 1–8). The ISA determined that the currently available evidence for additional endpoints is “suggestive” of causal relationships with short-term (central nervous system effects) and long-term exposures (cardiovascular effects, reproductive and developmental effects, central nervous system effects and total mortality) to ambient O<sub>3</sub>.

Consistent with emphasis in past reviews on O<sub>3</sub> 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 determined in the ISA to be caused by, or likely to be caused by, O<sub>3</sub> exposures (U.S. EPA, 2013, section 2.5.2). This preamble section summarizes the evidence for health effects attributable to O<sub>3</sub> exposures, with a focus on respiratory morbidity and mortality

<sup>15</sup> In determining that a causal relationship exists for O<sub>3</sub> 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, 2013, p. lxiv).

<sup>16</sup> In determining a “likely to be causal” relationship exists for O<sub>3</sub> 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, 2013, p. lxiv).

effects attributable to short- and long-term exposures, and cardiovascular system effects (including mortality) and total mortality attributable to short-term exposures (from section II.B in the proposal, 79 FR 75246–75271).

The information highlighted here is based on the assessment of the evidence in the ISA (U.S. EPA, 2013, Chapters 4 to 8) and consideration of that evidence 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<sub>3</sub> in the ambient air. This section summarizes: (1) Information available on potential mechanisms for health effects associated with exposure to O<sub>3</sub> (II.A.1.a); (2) the nature of effects that have been associated directly with both short- and long-term exposure to O<sub>3</sub> and indirectly with the presence of O<sub>3</sub> in ambient air (II.A.1.b); (3) considerations related to the adversity of O<sub>3</sub>-attributable health effects (II.A.1.c); and (4) considerations in characterizing the public health impact of O<sub>3</sub>, including the identification of “at risk” populations (II.A.1.d).

### a. Overview of Mechanisms

This section briefly summarizes the characterization of the key events and pathways that contribute to health effects resulting from O<sub>3</sub> exposures, as discussed in the proposal (79 FR 75247, section II.B.1) and in the ISA (U.S. EPA, 2013, section 5.3).

Experimental evidence elucidating modes of action and/or mechanisms contributes to our understanding of the biological plausibility of adverse O<sub>3</sub>-related health effects, including respiratory effects and effects outside the respiratory system (U.S. EPA, 2013, Chapters 6 and 7). Evidence indicates that the initial key event is the formation of secondary oxidation products in the respiratory tract (U.S. EPA, 2013, 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<sub>3</sub> (U.S. EPA 2014c, at 3–3, 3–9). The resulting secondary oxidation products transmit signals to the epithelium, pain receptive nerve fibers and, if present, immune cells involved in allergic responses. The available evidence indicates that the effects of O<sub>3</sub> are mediated by components of ELF and by the multiple cell types in the respiratory tract. Oxidative stress is an implicit part of this initial key event.

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 which leads to lung function decrements; initiation of pulmonary inflammation; alteration of barrier epithelial function; sensitization of bronchial smooth muscle; modification of lung host defenses; airways remodeling; and modulation of autonomic nervous function which may alter cardiac function (U.S. EPA, 2013, section 5.3, Figure 5–8).

Persistent inflammation and injury, which are observed in animal models of chronic and quasi-continuous exposure to O<sub>3</sub>, are associated with airways remodeling (see section 7.2.3 of the ISA, U.S. EPA, 2013). Chronic quasi-continuous exposure to O<sub>3</sub> 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<sub>3</sub> (U.S. EPA, 2013, section 5.3.8). Extrapulmonary effects of O<sub>3</sub> occur in numerous organ systems, including the cardiovascular, central nervous, reproductive, and hepatic systems (U.S. EPA, 2013, sections 6.3 to 6.5 and sections 7.3 to 7.5).

Responses to O<sub>3</sub> exposure are variable within the population. Studies have shown a large range of pulmonary function (*i.e.*, spirometric) responses to O<sub>3</sub> among healthy young adults, while responses within an individual are relatively consistent over time. Other responses to O<sub>3</sub> have also been characterized by a large degree of interindividual variability, including airways inflammation. The mechanisms that may underlie the variability in responses seen among individuals are discussed in the ISA (U.S. EPA, 2013, section 5.4.2). Certain functional genetic polymorphisms, pre-existing conditions or diseases, nutritional status, lifestages, and co-exposures can contribute to altered risk of O<sub>3</sub>-induced effects. Experimental evidence for such O<sub>3</sub>-induced changes contributes to our understanding of the biological plausibility of adverse O<sub>3</sub>-related health effects, including a range of respiratory effects as well as effects outside the respiratory system (*e.g.*, cardiovascular effects) (U.S. EPA, 2013, Chapters 6 and 7).

### b. Nature of Effects

This section briefly summarizes the information presented in the proposal on respiratory effects attributable to short-term exposures (II.A.1.b.i), respiratory effects attributable to long-

term exposures (II.A.1.b.ii), cardiovascular effects attributable to short-term exposures (II.A.1.b.iii), and premature mortality attributable to short-term exposures (II.A.1.b.iv) (79 FR 75247, section II.B.2).

#### i. Respiratory Effects—Short-term Exposure

Controlled human exposure, animal toxicological, and epidemiologic studies available in the last review provided clear, consistent evidence of a causal relationship between short-term O<sub>3</sub> exposure and respiratory effects (U.S. EPA, 2006a). Recent studies evaluated since the completion of the 2006 AQCD support and expand upon the strong body of evidence available in the last review (U.S. EPA, 2013, section 6.2.9).

Key aspects of this evidence are discussed below with regard to (1) lung function decrements; (2) pulmonary inflammation, injury, and oxidative stress; (3) airway hyperresponsiveness; (4) respiratory symptoms and medication use; (5) lung host defense; (6) allergic and asthma-related responses; (7) hospital admissions and emergency department visits; and (8) respiratory mortality.<sup>17</sup>

#### Lung Function Decrements

Lung function decrements are typically measured by spirometry and refer to reductions in the maximal amount of air that can be forcefully exhaled. Forced expiratory volume in 1 second (FEV<sub>1</sub>) is a common index used to assess the effect of O<sub>3</sub> on lung function. The ISA summarizes the currently available evidence from multiple controlled human exposure studies evaluating changes in FEV<sub>1</sub> following 6.6-hour O<sub>3</sub> exposures in young, healthy adults engaged in moderate levels of physical activity<sup>18</sup> (U.S. EPA, 2013, section 6.2.1.1, Figure 6–1). Exposures to an average O<sub>3</sub> concentration of 60 ppb results in group mean decrements in FEV<sub>1</sub> ranging from 1.8% to 3.6% (Adams, 2002; Adams, 2006;<sup>19</sup> Schelegle et al., 2009;<sup>20</sup> Kim et

al., 2011). The weighted average group mean decrement was 2.7% from these studies. 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).<sup>21</sup> Prolonged exposure to an average O<sub>3</sub> concentration of 72 ppb results in a statistically significant group mean decrement in FEV<sub>1</sub> of about 6% (Schelegle et al., 2009).<sup>22</sup> There is a smooth dose-response curve without evidence of a threshold for exposures between 40 and 120 ppb O<sub>3</sub> (U.S. EPA, 2013, Figure 6–1). When these data are taken together, the ISA concludes that “mean FEV<sub>1</sub> is clearly decreased by 6.6-hour exposures to 60 ppb O<sub>3</sub> and higher concentrations in [healthy, young adult] subjects performing moderate exercise” (U.S. EPA, 2013, p. 6–9).

As described in the proposal (79 FR 75250), the ISA focuses on individuals with >10% decrements in FEV<sub>1</sub> because (1) it is accepted by the American Thoracic Society (ATS) as an abnormal response and a reasonable criterion for assessing exercise-induced bronchoconstriction, and (2) some individuals in the Schelegle et al. (2009) study experienced 5–10% FEV<sub>1</sub> decrements following exposure to filtered air. The proportion of healthy adults experiencing FEV<sub>1</sub> decrements >10% following prolonged exposures to 80 ppb O<sub>3</sub> while at moderate exertion ranged from 17% to 29% and following exposures to 60 ppb O<sub>3</sub> ranged from 3% to 20%. The weighted average proportion (*i.e.*, based on numbers of subjects in each study) of young, healthy adults with >10% FEV<sub>1</sub> decrements is 25% following exposure to 80 ppb O<sub>3</sub> and 10% following exposure to 60 ppb O<sub>3</sub>, for 6.6 hours at moderate exertion (U.S. EPA, 2013, page 6–18 and 6–19).<sup>23</sup> Responses within an

<sup>21</sup> Adams (2006) did not find effects on FEV<sub>1</sub> 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<sub>1</sub> 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<sub>1</sub> for the 60 ppb protocol occurred after the sixth (and final) exercise period.

<sup>22</sup> As noted above, for the 70 ppb exposure group, Schelegle et al. (2009) reported that the actual mean exposure concentration was 72 ppb.

<sup>23</sup> 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

individual tend to be reproducible over a period of several months, reflecting differences in intrinsic responsiveness. Given this, the ISA concludes that “[t]hrough group mean decrements are biologically small and generally do not attain statistical significance, a considerable fraction of exposed individuals [in the clinical studies] experience clinically meaningful decrements in lung function” when exposed for 6.6 hours to 60 ppb O<sub>3</sub> during quasi-continuous, moderate exertion (U.S. EPA, 2013, 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 O<sub>3</sub> 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, described in more detail in the proposal (79 FR 75250), that included mathematical approaches to simulate the potential protective effect of antioxidants in the ELF at lower ambient O<sub>3</sub> concentrations, and that included a dose threshold below which changes in lung function do not occur. The resulting empirical models can estimate the frequency distribution of individual responses and summary measures of the distribution such as the mean or median response and the proportions of individuals with FEV<sub>1</sub> decrements >10%, 15%, and 20%.<sup>24</sup> The predictions of the models are consistent with the observed results from the individual controlled human exposure studies of O<sub>3</sub>-induced FEV<sub>1</sub> decrements (79 FR 75250–51, see also U.S. EPA, 2013, Figures 6–1 and 6–3). CASAC agreed that these models mark a significant technical advance over the exposure-response modeling approach used for the lung function risk assessment in the last review and explicitly found that “[t]he MSS model to be scientifically and biologically defensible” (Frey, 2014a, pp. 8, 2). CASAC also stated that “the comparison of the MSS model results to those obtained with the exposure-response model is of tremendous importance. Typically, the MSS model gives a result about a factor of three higher . . . for school-age children, which is expected because the MSS model includes

experience clinically meaningful changes in lung function following exposure for 6.6 hours to 60 ppb O<sub>3</sub> during quasi-continuous moderate exertion (U.S. EPA, 2012, section 6.2.1.1).

<sup>24</sup> One of these models, the McDonnell-Stewart-Smith (MSS) model (McDonnell et al. 2012) was used to estimate the occurrences of lung function decrements in the HREA.

<sup>17</sup> 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).

<sup>18</sup> Table 6–1 of the ISA includes descriptions of the activity levels evaluated in controlled human exposure studies (U.S. EPA, 2013).

<sup>19</sup> Adams (2006); (2002) both provide data for an additional group of 30 healthy subjects that were exposed via facemask to 60 ppb O<sub>3</sub> for 6.6 hours with moderate exercise. These subjects are described on page 133 of Adams (2006) and pages 747 and 761 of Adams (2002). The facemask exposure is not expected to affect the FEV<sub>1</sub> responses relative to a chamber exposure.

<sup>20</sup> For the 60 ppb target exposure concentration, Schelegle et al. (2009) reported that the actual mean exposure concentration was 63 ppb.

responses for a wider range of exposure protocols” (Frey, 2014a, pp. 8, 2).

Epidemiologic studies have consistently linked short-term increases in ambient O<sub>3</sub> concentrations with lung function decrements in diverse populations and lifestyles, including children attending summer camps, adults exercising or working outdoors, and groups with pre-existing respiratory diseases such as asthmatic children (U.S. EPA, 2013, section 6.2.1.2). Some of these studies reported O<sub>3</sub>-associated lung function decrements accompanied by respiratory symptoms<sup>25</sup> in asthmatic children. In contrast, studies of children in the general population have reported similar O<sub>3</sub>-associated lung function decrements but without accompanying respiratory symptoms (79 FR 75251; U.S. EPA, 2013, section 6.2.1.2). As noted in the PA (EPA, 2014c, pp. 4–70 to 4–71), additional research is needed to evaluate responses of people with asthma and healthy people in the 40 to 70 ppb range. Further epidemiologic studies and meta-analyses of the effects of O<sub>3</sub> exposure on children will help elucidate the concentration-response functions for lung function and respiratory symptom effects at lower O<sub>3</sub> concentrations.

Several epidemiologic panel studies<sup>26</sup> reported statistically significant associations with lung function decrements at relatively low ambient O<sub>3</sub> concentrations. For outdoor recreation or exercise, associations were reported in analyses restricted to 1-hour average O<sub>3</sub> concentrations less than 80 ppb, down to less than 50 ppb. Among outdoor workers, Brauer et al. (1996) found a robust association with daily 1-hour max O<sub>3</sub> concentrations less than 40 ppb. Ulmer et al. (1997) found a robust association in schoolchildren with 30-minute maximum O<sub>3</sub> concentrations less than 60 ppb. For 8-hour average O<sub>3</sub> 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).

As described in the proposal (79 FR 75251), several epidemiologic panel studies provided information on potential confounding by copollutants and most O<sub>3</sub> effect estimates for lung function were robust to adjustment for temperature, humidity, and copollutants

such as particulate matter with mass median aerodynamic diameter less than or equal to 2.5 micrometers (PM<sub>2.5</sub>), particulate matter with mass median aerodynamic diameter less than or equal to 10 micrometers (PM<sub>10</sub>), NO<sub>2</sub>, or sulfur dioxide (SO<sub>2</sub>) (Hoppe et al., 2003; Brunekreef et al., 1994; Hoek et al. 1993; U.S. EPA, 2013, pp. 6–67 to 6–69). Although examined in only a few epidemiologic studies, O<sub>3</sub> also remained associated with decreases in lung function with adjustment for pollen or acid aerosols (79 F 75251; U.S. EPA, 2013, section 6.2.1.2).

#### Pulmonary Inflammation, Injury and Oxidative Stress

As described in detail in section II.B.2.a.ii of the proposal (79 FR 75252), O<sub>3</sub> exposures can 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<sub>3</sub>-induced inflammation. As noted in the ISA (U.S. EPA, 2013, section 6.2.3), O<sub>3</sub> 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<sub>3</sub> can have several potential outcomes, ranging from resolving entirely following a single exposure to becoming a chronic inflammatory state, as described in detail in section II.B.2.a.ii of the proposal (79 FR 75252) and in the ISA (U.S. EPA, 2013, section 6.2.3). Continued cellular damage due to chronic inflammation “may alter the structure and function of pulmonary tissues” (U.S. EPA, 2013, p. 6–161). Lung injury and the resulting inflammation provide a mechanism by which O<sub>3</sub> may cause other more serious morbidity effects (e.g., asthma exacerbations) (U.S. EPA, 2013, section 6.2.3).<sup>27</sup>

Building on the last review, recent studies continue to support the evidence for airway inflammation and injury with new evidence for such effects following exposures to lower concentrations than had been evaluated previously. These studies include recent controlled human exposure and epidemiologic studies and are discussed more below.

An extensive body of evidence from controlled human exposure studies, described in section II.B.2.a.ii of the proposal, indicates that short-term exposures to O<sub>3</sub> can cause pulmonary inflammation and increases in polymorphonuclear leukocyte (PMN) influx and permeability following 80–600 O<sub>3</sub> ppb exposures, eosinophilic inflammation following exposures at or above 160 ppb, and O<sub>3</sub>-induced PMN influx following exposures of healthy adults to 60 ppb O<sub>3</sub>, the lowest concentration that has been evaluated for inflammation. A meta-analysis of 21 controlled human exposure studies (Mudway and Kelly, 2004) using varied experimental protocols (80–600 ppb O<sub>3</sub> exposures; 1–6.6 hours exposure duration; light to heavy exercise; bronchoscopy at 0–24 hours post-O<sub>3</sub> exposure) reported that PMN influx in healthy subjects is linearly associated with total O<sub>3</sub> dose.

As with FEV<sub>1</sub> responses to O<sub>3</sub>, inflammatory responses to O<sub>3</sub> are generally reproducible within individuals, with some individuals experiencing more severe O<sub>3</sub>-induced airway inflammation than indicated by group averages. Unlike O<sub>3</sub>-induced decrements in lung function, which are attenuated following repeated exposures over several days, some markers of O<sub>3</sub>-induced inflammation and tissue damage remain elevated during repeated exposures, indicating ongoing damage to the respiratory system (79 FR 75252). Most controlled human exposure studies have reported that asthmatics experience larger O<sub>3</sub>-induced inflammatory responses than non-asthmatics.<sup>28</sup>

In the previous review (U.S. EPA, 2006a), the epidemiologic evidence of O<sub>3</sub>-associated changes in airway inflammation and oxidative stress was limited (79 FR 75253). Since then, as a result of the development of less invasive test methods, there has been a large increase in the number of studies assessing ambient O<sub>3</sub>-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, 2013, section 6.2.3.2). These recent studies form a larger database to establish coherence with findings from controlled human exposure and animal

<sup>25</sup> Reversible loss of lung function in combination with the presence of symptoms meets ATS criteria for adversity (ATS, 2000a).

<sup>26</sup> Panel studies include repeated measurements of health outcomes, such as respiratory symptoms, at the individual level (U.S. EPA, 2013, p. 1x).

<sup>27</sup> CASAC also addressed this issue: “The CASAC believes that these modest changes in FEV<sub>1</sub> 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).

<sup>28</sup> When evaluated, these studies have also reported O<sub>3</sub>-induced respiratory symptoms in asthmatics. Specifically, Scannell et al. (1996), Basha et al. (1994), and Vagaggini et al. (2001, 2007) reported increased symptoms in addition to inflammation.

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<sub>3</sub> concentrations and respiratory symptoms and asthma exacerbations.

#### Airway Hyperresponsiveness (AHR)

A strong body of controlled human exposure and animal toxicological studies, most of which were available in the last review of the O<sub>3</sub> NAAQS, report O<sub>3</sub>-induced AHR after either acute or repeated exposures (U.S. EPA, 2013, section 6.2.2.2). People with asthma often exhibit increased airway responsiveness at baseline relative to healthy control subjects, and asthmatics can experience further increases in responsiveness following exposures to O<sub>3</sub>. Studies reporting increased airway responsiveness after O<sub>3</sub> exposure contribute to a plausible link between ambient O<sub>3</sub> exposures and increased respiratory symptoms in asthmatics, and increased hospital admissions and emergency department visits for asthma (section II.B.2.a.iii, 79 FR 75254; U.S. EPA, 2013, section 6.2.2.2).

#### 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 to seek medical care. Studies evaluating the link between O<sub>3</sub> exposures and such symptoms allow a direct characterization of the clinical and public health significance of ambient O<sub>3</sub> exposure. Controlled human exposure and toxicological studies have described modes of action through which short-term O<sub>3</sub> exposures may increase respiratory symptoms by demonstrating O<sub>3</sub>-induced AHR (U.S. EPA, 2013, section 6.2.2) and pulmonary inflammation (U.S. EPA, 2013, section 6.2.3).

The link between subjective respiratory symptoms and O<sub>3</sub> 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<sub>3</sub> concentrations at or above 80 ppb. In addition, one study reported such symptoms following exposures to 60 ppb O<sub>3</sub>, though the increase was not statistically different from filtered air controls. Epidemiologic studies reported associations between ambient O<sub>3</sub> and

respiratory symptoms and medication use in a variety of locations and populations, including asthmatic children living in U.S. cities (U.S. EPA, 2013, pp. 6–1 to 6–2). In the current review, additional controlled human exposure studies have evaluated respiratory symptoms following exposures to O<sub>3</sub> concentrations below 80 ppb and recent epidemiologic studies have evaluated associations with respiratory symptoms and medication use (U.S. EPA, 2013, sections 6.2.1, 6.2.4).

As noted in section II.B.2.a.iv in the proposal (79 FR 75255), the findings for O<sub>3</sub>-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<sub>3</sub> concentration and increases in respiratory symptoms (U.S. EPA, 2013, section 6.2.4).

Most epidemiologic studies of O<sub>3</sub> and respiratory symptoms and medication use have been conducted in children and/or adults with asthma, with fewer studies, and less consistent results, in non-asthmatic populations (U.S. EPA, 2013, section 6.2.4). The 2006 AQCD (U.S. EPA, 2006a; U.S. EPA, 2013, section 6.2.4) concluded that the collective body of epidemiologic evidence indicated that short-term increases in ambient O<sub>3</sub> 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<sub>3</sub> concentrations and increased respiratory symptoms and asthma medication use in children with asthma (U.S. EPA, 2013, Figure 6–12, Table 6–20, section 6.2.4.1). Methodological differences, described in section II.B.2.a.iv of the proposal, among studies make comparisons across recent multicity studies of respiratory symptoms difficult.

Available evidence indicates that O<sub>3</sub>-associated increases in respiratory symptoms are not confounded by temperature, pollen, or copollutants (primarily PM) (U.S. EPA, 2013, section 6.2.4.5; Table 6–25). However, identifying the independent effects of O<sub>3</sub> in some studies was complicated due to the high correlations observed between O<sub>3</sub> 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<sub>3</sub> exposure, provide substantial evidence supporting the independent effects of short-term ambient O<sub>3</sub> exposure on respiratory symptoms (U.S. EPA, 2013, section 6.2.4.5).

In summary, both controlled human exposure and epidemiologic studies have reported respiratory symptoms attributable to short-term O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub>. As was concluded in the last review, the collective body of epidemiologic evidence indicates that short-term increases in ambient O<sub>3</sub> concentration are associated with increases in respiratory symptoms in children with asthma (U.S. EPA, 2013, 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<sub>3</sub> concentration were associated with increases in respiratory symptoms in adults with asthma.

#### 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. Based on toxicological and human exposure studies, in the last review EPA concluded that available evidence indicates that short-term O<sub>3</sub> 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<sub>3</sub> effects, the effects of particles, and respiratory infections (U.S. EPA, 2006a).

Relatively few studies conducted since the last review have evaluated the effects of O<sub>3</sub> exposures on lung host defense. As presented in section II.B.2.a.v of the proposal (79 FR 75256),



when the available evidence is taken as a whole, the ISA concludes that acute O<sub>3</sub> 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<sub>3</sub> could be predisposed to bacterial infections in the lower respiratory tract.

#### Allergic and Asthma Related Responses

Evidence from controlled human exposure and epidemiologic studies available in the last review indicates that O<sub>3</sub> exposure skews immune responses toward an allergic phenotype and could also make airborne allergens more allergenic, as discussed in more detail in the proposal (79 FR 75257). Evidence from controlled human exposure and animal toxicology studies available in the last review indicates that O<sub>3</sub> may also increase AHR to specific allergen triggers (75 FR 2970, January 19, 2010). When combined with NO<sub>2</sub>, O<sub>3</sub> has been shown to enhance nitration of common protein allergens, which may increase their allergenicity (Franze et al., 2005).

#### Hospital Admissions and Emergency Department Visits

The 2006 AQCD concluded that “the overall evidence supports a causal relationship between acute ambient O<sub>3</sub> exposures and increased respiratory morbidity resulting in increased emergency department visits and [hospital admissions] during the warm season”<sup>29</sup> (U.S. EPA, 2006a). This conclusion was “strongly supported by the human clinical, animal toxicologic[al], and epidemiologic evidence for [O<sub>3</sub>-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 AQCD (U.S. EPA, 2013, section 6.2.7). Since the completion of the 2006 AQCD, relatively fewer studies, conducted in the U.S., Canada, and Europe, have evaluated associations between short-term O<sub>3</sub> concentrations and respiratory hospital admissions and emergency department visits, with a growing

<sup>29</sup> Epidemiologic associations for O<sub>3</sub> are more robust during the warm season than during cooler months (e.g., smaller measurement error, less potential confounding by copollutants). The rationale for focusing on warm season epidemiologic studies for O<sub>3</sub> can be found at 72 FR 37838–37840.

number of studies conducted in Asia. This epidemiologic evidence is discussed in detail in the proposal (79 FR 75258) and in the ISA (U.S. EPA, 2013, section 6.2.7).<sup>30</sup>

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, 2013, 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<sub>3</sub>-related health effects but were not evaluated in the larger studies (U.S. EPA, 2013, section 6.2.7.1). When examining the association between short-term O<sub>3</sub> 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, 2013, section 6.2.7.1).

The collective evidence across studies indicates a mostly consistent positive association between O<sub>3</sub> exposure and respiratory-related hospital admissions and emergency department visits. Moreover, 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<sub>3</sub> effect estimates remained relatively robust upon the inclusion of PM and gaseous pollutants in two-pollutant models (U.S. EPA, 2013, 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

<sup>30</sup> The consideration of ambient O<sub>3</sub> 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 for alternative standards, respectively.

al., 2006; U.S. EPA, 2013, section 6.2.7.5).<sup>31</sup>

In the last review, studies had not evaluated the concentration-response relationship between short-term O<sub>3</sub> exposure and respiratory-related hospital admissions and emergency department visits. As described in the proposal in section II.B.2.a.vii (79 FR 75257) and in the ISA (U.S. EPA, 2013, section 6.2.7.2), 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<sub>3</sub> exposure and asthma hospital admissions (Silverman and Ito, 2010; Strickland et al., 2010). In addition, an examination of the concentration-response relationship for O<sub>3</sub> exposure and pediatric asthma emergency department visits found no evidence of a threshold at O<sub>3</sub> concentrations as low as 30 ppb (for daily maximum 8-hour concentrations) (U.S. EPA, 2013, section 6.2.7.3). However, in these studies there is uncertainty in the shape of the concentration-response curve at the lower end of the distribution of O<sub>3</sub> concentrations due to the low density of data in this range. Further studies at low-level O<sub>3</sub> exposures might reduce this uncertainty.

#### Respiratory Mortality

Evidence from experimental studies indicates multiple potential pathways of respiratory effects from short-term O<sub>3</sub> exposures, which support the continuum of respiratory effects that could potentially result in respiratory-related mortality in adults (U.S. EPA, 2013, section 6.2.8).<sup>32</sup> The evidence in the last review was inconsistent for associations between short-term O<sub>3</sub> concentrations and respiratory mortality (U.S. EPA, 2006a). New epidemiologic evidence for respiratory mortality is discussed in detail in the ISA (U.S. EPA, 2013, section 6.6) and summarized below. The majority of recent multicity studies have reported positive associations between short-term O<sub>3</sub> exposures and respiratory mortality, particularly during the summer months (U.S. EPA, 2013, Figure 6–36).

<sup>31</sup> The ISA concluded that, “[o]verall, recent studies provide copollutant results that are consistent with those from the studies evaluated in the 2006 O<sub>3</sub> AQCD [(U.S. EPA, 2006[a]), Figure 7–12, page 7–80 of the 2006 O<sub>3</sub> AQCD], which found that O<sub>3</sub> respiratory hospital admissions risk estimates remained robust to the inclusion of PM in copollutant models (U.S. EPA, 2013, pp. 6–152 to 6–153).

<sup>32</sup> Premature mortality is discussed in more detail below in section II.A.1.b.iv.



Recent multicity studies from the U.S. (Zanobetti and Schwartz, 2008), 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<sub>3</sub> concentrations and respiratory mortality (U.S. EPA, 2013, 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 two studies analyzed the potential for copollutant confounding of the O<sub>3</sub>-respiratory mortality relationship (Katsouyanni et al., (2009); Stafoggia et al., (2010)). Based on the results of these analyses, the O<sub>3</sub> respiratory mortality risk estimates appear to be moderately to substantially sensitive (e.g., increased or attenuated) to inclusion of PM<sub>10</sub>. However, in the APHENA study (Katsouyanni et al., 2009), the mostly every-6th-day sampling schedule for PM<sub>10</sub> in the Canadian and U.S. datasets greatly reduced their sample size and limits the interpretation of these results (U.S. EPA, 2013, sections 6.2.8 and 6.2.9).

The evidence for associations between short-term O<sub>3</sub> concentrations and 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.

#### ii. Respiratory Effects—Long-Term Exposure

Since the last review, the body of evidence indicating the occurrence of respiratory effects due to long-term O<sub>3</sub> exposure has been strengthened. This evidence is discussed in detail in the ISA (U.S. EPA, 2013, Chapter 7) and summarized below for new-onset asthma and asthma prevalence, asthma hospital admissions, pulmonary structure and function, and respiratory mortality.

Asthma is a heterogeneous disease with a high degree of temporal variability. The onset, 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<sub>3</sub> exposures and the onset of asthma in adults and children indicated

a direct effect of long-term O<sub>3</sub> exposures on asthma risk in adults and effect modification by O<sub>3</sub> in children. Since then, 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<sub>3</sub> 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. For this review, 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<sub>3</sub> communities. Described in detail in the proposal (79 FR 75259) and in the ISA (U.S. EPA, 2013, section 7.2.1), 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. Cross-sectional studies by Akinbami et al. (2010) and Hwang et al. (2005) provide further evidence relating O<sub>3</sub> exposures with asthma prevalence. Gene-environment interactions are discussed in detail in Section 5.4.2.1 in the ISA (U.S. EPA, 2013).

In the 2006 AQCD (U.S. EPA, 2006a), studies on O<sub>3</sub>-related hospital discharges and emergency department visits for asthma and respiratory disease mainly looked at short-term (daily) metrics. Recent studies 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.

In the 2006 AQCD (U.S. EPA, 2006a), few epidemiologic studies had investigated the effect of chronic O<sub>3</sub> exposure on pulmonary function. As discussed in the proposal, epidemiologic studies of long-term exposures in both children and adults provide mixed results about the effects of long-term O<sub>3</sub> exposure on pulmonary function and the growth rate of lung function.

Long-term studies in animals allow for greater insight into the potential effects of prolonged exposure to O<sub>3</sub> that may not be easily measured in humans, such as structural changes in the respiratory tract. Despite uncertainties, epidemiologic studies observing associations of O<sub>3</sub> exposure with

functional changes in humans can attain biological plausibility in conjunction with long-term toxicological studies, particularly O<sub>3</sub>-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, 2013), have used nonhuman primates to examine the effect of O<sub>3</sub> alone, or in combination with an inhaled allergen, house dust mite antigen, 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<sub>3</sub> (U.S. EPA, 2013, section 7.2.3.2). As discussed in more detail in the proposal, the studies provide evidence of an O<sub>3</sub>-induced change in airway resistance and responsiveness and provide biological plausibility of long-term exposure, or repeated short-term exposures, to O<sub>3</sub> contributing to the effects of asthma in children.

Collectively, evidence from animal studies strongly suggests that chronic O<sub>3</sub> 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<sub>3</sub>-induced morphological changes and the mechanisms involved in lifestage susceptibility and developmental effects can be found in the ISA (U.S. EPA, 2013, section 5.3.7, section 5.4.2.4). The findings reported in chronic animal studies offer insight into potential biological mechanisms for the suggested association between seasonal O<sub>3</sub> exposure and reduced lung function development in children as observed in epidemiologic studies (U.S. EPA, 2013, section 7.2.3.1). Further research could help fill in the gaps in our understanding of the mechanisms involved in lifestage susceptibility and developmental effects in children of seasonal or long-term exposure to O<sub>3</sub>.

A limited number of epidemiologic studies have assessed the relationship between long-term exposure to O<sub>3</sub> and mortality in adults. The 2006 AQCD concluded that an insufficient amount of evidence existed "to suggest a causal relationship between chronic O<sub>3</sub> 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 a recent follow-up analysis of the American Cancer Society 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<sub>3</sub> exposure was associated with the risk of death from respiratory causes, and this effect was robust to the inclusion of PM<sub>2.5</sub>. 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<sub>3</sub>-related effects, observed an association between long-term (warm season) exposure to O<sub>3</sub> and elevated risk of mortality in the cohort that had previously experienced an emergency hospital admission due to chronic obstructive pulmonary disease (COPD). A key limitation of this study is the inability to control for PM<sub>2.5</sub>, because data were not available in these cities until 1999.

### iii. Cardiovascular Effects—Short-Term Exposure

A relatively small number of studies have examined the potential effect of short-term O<sub>3</sub> exposure on the cardiovascular system. The 2006 AQCD (U.S. EPA, 2006a, p. 8–77) concluded that “O<sub>3</sub> 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<sub>3</sub> on the cardiovascular system has expanded. There is an emerging body of animal toxicological evidence demonstrating that short-term exposure to O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub>-related cardiovascular events and are summarized in the ISA (U.S. EPA, 2013, section 6.3).

Controlled human exposure studies discussed in previous reviews 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<sub>3</sub> exposure (U.S. EPA, 2013, 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<sub>3</sub>-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<sub>3</sub> exposures. Increases and decreases in high frequency heart rate variability (HRV) have been reported. These changes in cardiac function observed in animal and human studies provide preliminary evidence for O<sub>3</sub>-induced modulation of the autonomic nervous system through the activation of neural reflexes in the lung (U.S. EPA, 2013, section 5.3.2).

Overall, the ISA concludes that the available body of epidemiologic evidence examining the relationship between short-term exposures to O<sub>3</sub> concentrations and cardiovascular morbidity is inconsistent (U.S. EPA, 2013, section 6.3.2.9).

Despite the inconsistent evidence for an association between O<sub>3</sub> concentration and cardiovascular disease (CVD) morbidity, mortality studies indicate a consistent positive association between short-term O<sub>3</sub> 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<sub>3</sub>. Additionally, there is some evidence for an association between long-term exposure to O<sub>3</sub> and mortality, although the association between long-term ambient O<sub>3</sub> concentrations and cardiovascular mortality can be confounded by other pollutants (U.S. EPA, 2013). The ISA (U.S. EPA, 2013, 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<sub>3</sub> and cardiovascular system effects.

### iv. Premature Mortality—Short-Term Exposure

The 2006 AQCD concluded that the overall body of evidence was highly suggestive that short-term exposure to O<sub>3</sub> 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, 2006a; U.S. EPA, 2013, p. 2–18). In building on the evidence for mortality from the last review, the ISA states (U.S. EPA, 2013, p. 6–261):

The evaluation of new multicity studies that examined the association between short-term O<sub>3</sub> exposures and mortality found evidence that supports the conclusions of the 2006 AQCD. These new studies reported consistent positive associations between short-term O<sub>3</sub> 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<sub>3</sub> exposure and cardiovascular and respiratory mortality.

The 2006 AQCD reviewed a large number of time-series studies of associations between short-term O<sub>3</sub> exposures and total mortality including single- and multicity studies, and meta-analyses. Available studies reported some evidence for heterogeneity in O<sub>3</sub> mortality risk estimates across cities and across studies. Studies that conducted seasonal analyses reported larger O<sub>3</sub> mortality risk estimates during the warm or summer season. Overall, the 2006 AQCD identified robust associations between various measures of daily ambient O<sub>3</sub> 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<sub>3</sub> exposure and cardiovascular mortality, with less consistent evidence for associations with respiratory mortality. The majority of the evidence for associations between O<sub>3</sub> 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 AQCD concluded that “the overall body of evidence is highly suggestive that O<sub>3</sub> directly or indirectly contributes to nonaccidental and cardiopulmonary-related mortality” (U.S. EPA, 2013, section 6.6.1).

Recent studies have strengthened the body of evidence that supports the association between short-term O<sub>3</sub> 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<sub>3</sub> concentrations and all-cause mortality, with evidence for larger mortality risk estimates during the warm or summer months (79 FR 75262; U.S. EPA, 2013 Figure 6–27; Table 6–42). Similarly, evaluations of cause-specific mortality have reported consistently positive associations with O<sub>3</sub>, particularly in analyses restricted to the warm season (79 FR 75262; U.S. EPA, 2013 Fig. 6–37; Table 6–53).

In the previous review, multiple uncertainties remained regarding the relationship between short-term O<sub>3</sub> concentrations and mortality, including the extent of residual confounding by copollutants; characterization of the factors that modify the O<sub>3</sub>-mortality association; the appropriate lag structure for identifying O<sub>3</sub>-mortality effects; and the shape of the O<sub>3</sub>-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 and are described in more detail in the proposal (79 FR 75262 and in the ISA (U.S. EPA, 2013, section 6.6.2).

In particular, recent studies have evaluated different statistical approaches to examine the shape of the O<sub>3</sub>-mortality concentration-response relationship and to evaluate whether a threshold exists for O<sub>3</sub>-related mortality. These studies are detailed in the proposal (79 FR 75262) and in the ISA (U.S. EPA, 2013, p. 2–32). The ISA reaches the following overall conclusions that the epidemiologic studies identified in the ISA indicated a generally linear C–R function with no indication of a threshold but that there is a lack of data at lower O<sub>3</sub> concentrations and therefore, less certainty in the shape of the C–R curve at the lower end of the distribution (U.S. EPA, 2013, p. 2–32).

### c. Adversity of Effects

In making judgments as to when various O<sub>3</sub>-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 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, 2000a), 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 more recent guidance concludes that transient, reversible loss of lung function in combination with respiratory symptoms should be considered adverse.<sup>33</sup> However, the committee also recommended “that a small, transient loss of lung function, by itself, should not automatically be designated as adverse” (ATS, 2000a, p. 670).

There is also a more specific consideration of population risk in the 2000 guidance. Specifically, the committee considered that a shift in the risk factor distribution, and hence the risk profile of the exposed population, should be considered adverse, even in the absence of the immediate occurrence of frank illness (ATS, 2000a, p. 668). 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 of lung function 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 already have diminished reserve function, and therefore would be at increased risk to further environmental insult (ATS, 2000a, p. 668).

The ATS also concluded in its guidance that elevations of biomarkers such as cell numbers and 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

<sup>33</sup> “In drawing the distinction between adverse and nonadverse reversible effects, this committee recommended that reversible loss of lung function in combination with the presence of symptoms should be considered as adverse” (ATS, 2000a).

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).

Application of the ATS guidelines to the least serious category of effects<sup>34</sup> related to ambient O<sub>3</sub> exposures, which are also the most numerous and, therefore, are also 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<sub>1</sub> 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 by the EPA in the 1997 O<sub>3</sub> NAAQS review and slightly revised in the 2008 review (U.S. EPA, 1996b, p. 59; U.S. EPA, 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<sub>3</sub> Staff Paper (U.S. EPA, 2007, pp. 3–74 to 3–75).

For the purpose of estimating potentially adverse lung function decrements in active healthy people, the CASAC panel in the 2008 O<sub>3</sub> NAAQS 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<sub>1</sub> decrements ≥15% but <20%) (Henderson, 2006; U.S. EPA, 2007, p. 3–76). In this review, CASAC reiterated that the “[e]stimation of FEV<sub>1</sub> decrements of ≥15% is appropriate as a scientifically relevant surrogate for adverse health outcomes in active healthy adults” (Frey, 2014c, p. 3).

For the purpose of estimating potentially adverse lung function decrements in people with lung disease, the CASAC panel in the 2008 O<sub>3</sub> NAAQS review indicated that a focus on the lower end of the range of moderate levels of functional responses is most appropriate (*e.g.*, FEV<sub>1</sub> decrements ≥10%) (Henderson, 2006; U.S. EPA, 2007, p. 3–76). In their letter

<sup>34</sup> These include, for example, the transient and reversible effects demonstrated in controlled human exposure studies, such as lung function decrements or respiratory symptoms.

advising the Administrator on the reconsideration of the 2008 final decision, CASAC stated that “[a] 10% decrement in FEV<sub>1</sub> 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<sub>1</sub>) such that a ≥ 10% decrement could lead to moderate to severe respiratory symptoms” (Samet, 2011). In this review, CASAC provided similar advice, stating that “[a]n FEV<sub>1</sub> decrement of ≥ 10% is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease”, and that such decrements “could be adverse for people with lung disease” (Frey, 2014c, pp. 3, 7).

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). While 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. In particular, not every estimated occurrence of an O<sub>3</sub>-induced FEV<sub>1</sub> decrement will be adverse.<sup>35</sup> However, 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 (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, as in the current review (II.B, II.C below), 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).

#### d. Ozone-Related Impacts on Public Health

The currently available evidence expands the understanding of populations that were identified to be at greater risk of O<sub>3</sub>-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<sub>3</sub>) and supports the identification of additional factors that may lead to increased risk (U.S. EPA, 2006a, section 6.3; U.S. EPA, 2013, Chapter 8). Populations and lifestages may be at greater risk for O<sub>3</sub>-related health effects due to factors that contribute to their susceptibility and/or vulnerability to O<sub>3</sub>. 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, 2013, p. 8–1; U.S. EPA, 2010, 2009b). In some cases, the terms “at-risk” and “sensitive” have been used to encompass these concepts more generally. In the ISA, PA, and proposal, “at-risk” is the all-encompassing term used to define groups with specific factors that increase their risk of O<sub>3</sub>-related health effects.

There are multiple avenues by which groups may experience increased risk for O<sub>3</sub>-induced health effects. A population or lifestage<sup>36</sup> may exhibit greater effects than other populations or lifestages exposed to the same 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<sub>3</sub> concentrations. This would include, for example, groups of people with greater exposure

to ambient O<sub>3</sub> 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<sub>3</sub> days. Some groups may be at increased risk of O<sub>3</sub>-related health effects through a combination of factors. For example, children tend to spend more time outdoors when O<sub>3</sub> 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, 2013, Chapter 8). An at-risk population or lifestage is more likely to experience adverse health effects related to O<sub>3</sub> exposures and/or, develop more severe effects from exposure than the general population. The populations and lifestages identified by the ISA (U.S. EPA, 2013, section 8.5) identified that have “adequate” evidence for increased O<sub>3</sub>-related health effects are people with certain genotypes, people with asthma, younger and older age groups, people with reduced intake of certain nutrients, and outdoor workers. These at-risk populations and lifestages are described in more detail in section II.B.4 of the proposal (79 FR 75264–269).

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<sub>3</sub>-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<sub>3</sub>-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, 2013, 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

<sup>35</sup> As noted above, the ATS recommended “that a small, transient loss of lung function, by itself, should not automatically be designated as adverse” (ATS, 2000a, p. 670).

<sup>36</sup> 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.

children have reported currently having asthma (Bloom et al., 2011).<sup>37</sup>

With regard to lifestyles, 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<sub>3</sub> 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).<sup>38</sup> Of these, approximately 7.4% of the workforce, or about 7.8 million people, worked outdoors three or more days per week.

While it is difficult to estimate the total number of people in groups that are at greater risk from exposure to O<sub>3</sub>, due to the overlap in members of the different at-risk population groups, the proportion of the total population at greater risk is large. The size of the at-risk population combined with the estimates of risk of different health outcomes associated with exposure to O<sub>3</sub> can give an indication of the magnitude of O<sub>3</sub> impacts on public health.

## 2. Overview of Human Exposure and Health Risk Assessments

To put judgments about health effects into a broader public health context, the EPA has developed and applied models to estimate human exposures to O<sub>3</sub> and O<sub>3</sub>-associated health risks. Exposure and risk estimates that are output from such models are presented and assessed in the HREA (U.S. EPA, 2014a). Section II.C of the proposal discusses the quantitative assessments of O<sub>3</sub> exposures and O<sub>3</sub>-related health risks that are presented in the HREA (79 FR

75270). Summaries of these discussions are provided below for the approach used to adjust air quality for quantitative exposure and risk analyses in the HREA (II.A.2.a), the HREA assessment of exposures to ambient O<sub>3</sub> (II.A.2.b), and the HREA assessments of O<sub>3</sub>-related health risks (II.A.2.c).

### a. Air Quality Adjustment

As discussed in section II.C.1 of the proposal (79 FR 75270), the HREA uses a photochemical model to estimate sensitivities of O<sub>3</sub> to changes in precursor emissions in order to estimate ambient O<sub>3</sub> concentrations that would just meet the current and alternative standards (U.S. EPA, 2014a, Chapter 4).<sup>39</sup> For the 15 urban study areas evaluated in the HREA,<sup>40</sup> this model-based adjustment approach estimates hourly O<sub>3</sub> concentrations at each monitor location when modeled U.S. anthropogenic precursor emissions (*i.e.*, NO<sub>x</sub>, VOC)<sup>41</sup> are reduced. The HREA estimates air quality that just meets the current and alternative standards for the 2006–2008 and 2008–2010 periods.<sup>42</sup>

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<sub>3</sub> concentrations. Compared to the quadratic rollback approach used in previous reviews, it provides more realistic estimates of the spatial and temporal responses of O<sub>3</sub> to reductions in precursor emissions. Because ambient NO<sub>x</sub> can contribute both to the formation and destruction of O<sub>3</sub> (U.S. EPA, 2014a, Chapter 4), the response of ambient O<sub>3</sub> concentrations to reductions in NO<sub>x</sub> emissions is more variable than

indicated by the quadratic rollback approach. This improved approach to adjusting O<sub>3</sub> air quality is consistent with recommendations from the National Research Council of the National Academies (NRC, 2008). In addition, CASAC strongly supported the new approach as an improvement and endorsed the way it was utilized in the HREA, 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).

Within urban study areas, the model-based air quality adjustments show reductions in the O<sub>3</sub> levels at the upper ends of ambient concentrations and increases in the O<sub>3</sub> levels at the lower ends of those distributions (U.S. EPA, 2014a, section 4.3.3.2, Figures 4–9 and 4–10).<sup>43</sup> Seasonal means of daily O<sub>3</sub> 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<sub>3</sub> 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).

As discussed in the PA (U.S. EPA, 2014c, section 3.2.1), adjusted patterns of O<sub>3</sub> air quality have important implications for exposure and risk estimates in urban case 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) will decrease with model-adjustment to the current and alternative standards. In contrast, seasonal risk estimates influenced by the full distribution of ambient O<sub>3</sub> concentrations (*i.e.*, epidemiology-based risk estimates, as discussed in section 3.2.3.2 of the PA) either increase or decrease in response to air quality adjustment, depending on the balance between the daily decreases in high O<sub>3</sub>

<sup>37</sup> As noted below (II.C.3.a.ii), asthmatics can experience larger O<sub>3</sub>-induced respiratory effects than non-asthmatic, healthy adults. The responsiveness of asthmatics to O<sub>3</sub> 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.

<sup>38</sup> 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/](http://www.onetonline.org/find/descriptor/browse/Work_Context/4.C.2/).

<sup>39</sup> The HREA uses the Community Multi-scale Air Quality (CMAQ) photochemical model instrumented with the higher order direct decoupled method (HDDM) to estimate O<sub>3</sub> concentrations that would occur with the achievement of the current and alternative O<sub>3</sub> standards (U.S. EPA, 2014a, Chapter 4).

<sup>40</sup> 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.

<sup>41</sup> Exposure and risk analyses for most of the urban study areas focus on reducing U.S. anthropogenic NO<sub>x</sub> 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<sub>x</sub> and VOC (U.S. EPA, 2014a, section 4.3.3.1; Appendix 4D).

<sup>42</sup> These estimates thus reflect design values—8 hour values using the form of the NAAQS that meet the level of the current or alternative standards. 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.

<sup>43</sup> It is important to note that sensitivity analyses in the HREA indicate that the increases in low O<sub>3</sub> concentrations are smaller when NO<sub>x</sub> and VOC emissions are reduced than when only NO<sub>x</sub> emissions are reduced (U.S. EPA, 2014a, Appendix 4–D, section 4.7).

concentrations and increases in low O<sub>3</sub> concentrations.<sup>44</sup>

To evaluate uncertainties in air quality adjustments, the HREA assessed the extent to which the modeled O<sub>3</sub> response to reductions in NO<sub>x</sub> emissions appropriately represent the trends observed in monitored ambient O<sub>3</sub> following actual reductions in NO<sub>x</sub> emissions, and the extent to which the O<sub>3</sub> 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<sub>3</sub> concentrations during a time period when the U.S. experienced large-scale reductions in NO<sub>x</sub> emissions (*i.e.*, 2001 to 2010). Analyses of trends in monitored O<sub>3</sub> indicate that over such a time period, the upper end of the distribution of monitored O<sub>3</sub> 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<sub>3</sub> 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 HREA, these increases in median concentrations likely reflect the increases in relatively low O<sub>3</sub> concentrations that can occur near important sources of NO<sub>x</sub> upon reductions in NO<sub>x</sub> emissions (U.S. EPA, 2014a, section 8.2.3.1). These patterns of monitored O<sub>3</sub> during a period when the U.S. experienced large reductions in NO<sub>x</sub> emissions are qualitatively consistent with the modeled responses of O<sub>3</sub> to reductions in NO<sub>x</sub> emissions.

To evaluate the second issue, the HREA assessed the O<sub>3</sub> air quality response to reducing both NO<sub>x</sub> and VOC emissions (*i.e.*, in addition to assessing reductions in NO<sub>x</sub> emissions alone) for a subset of seven urban study areas. As discussed in the PA (U.S. EPA, 2014c, section 3.2.1), the addition of VOC reductions generally resulted in larger decreases in mid-range O<sub>3</sub> concentrations (25th to 75th percentiles) (U.S. EPA, 2014a, Appendix 4D, section 4.7).<sup>45</sup> In addition, in all seven of the

urban study areas evaluated, the increases in low O<sub>3</sub> concentrations were smaller for the NO<sub>x</sub>/VOC scenarios than the NO<sub>x</sub> 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<sub>3</sub> concentrations (discussed below), these results suggest that in some locations optimized emissions reduction strategies could result in larger reductions in O<sub>3</sub>-associated mortality and morbidity than indicated by HREA estimates.

#### b. Exposure Assessment

As discussed in section II.C.2 of the proposal, the O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub>-attributable effects (U.S. EPA, 2013, Chapter 8; II.A.1.d, above). 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<sub>3</sub> NAAQS could be associated with exposures to O<sub>3</sub> concentrations reported to result in respiratory effects.<sup>46</sup> These analyses of exposure assessment incorporate behavior patterns, including estimates of physical exertion, which are critical in assessing whether ambient concentrations of O<sub>3</sub> may pose a public health risk.<sup>47</sup> In particular, exposures to

(U.S. EPA, 2014a, Appendix 4–D, section 4.7). In this analysis, emissions of NO<sub>x</sub> and VOC were reduced by equal percentages, a scenario not likely to reflect the optimal combination for reducing risks. In most of the urban study areas the inclusion of VOC emissions reductions did not alter the NO<sub>x</sub> emissions reductions required to meet the current or alternative standards. The exceptions are Chicago and Denver, for which the HREA risk estimates are based on reductions in both NO<sub>x</sub> and VOC (U.S. EPA, 2014a, section 4.3.3.1).

<sup>46</sup> In addition, the range of modeled personal exposures to ambient O<sub>3</sub> 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).

<sup>47</sup> See 79 FR 75269 “The activity pattern of individuals is an important determinant of their exposure. Variation in O<sub>3</sub> concentrations among various microenvironments means that the amount of time spent in each location, as well as the level

ambient or near-ambient O<sub>3</sub> concentrations have only been shown to result in potentially adverse effects if the ventilation rates of people in the exposed populations are raised to a sufficient degree (*e.g.*, through physical exertion) (U.S. EPA, 2013, section 6.2.1.1). Estimates of such “exposures of concern” provide perspective on the potential public health impacts of O<sub>3</sub>-related effects, including effects that cannot currently be evaluated in a quantitative risk assessment.<sup>48</sup>

The HREA estimates 8-hour exposures at or above benchmark concentrations of 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<sub>3</sub>-induced respiratory effects are known to occur in some healthy adults engaged in moderate, quasi-continuous exertion, based on evidence from controlled human exposure studies (U.S. EPA, 2013, 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<sub>3</sub> 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).

In considering estimates of O<sub>3</sub> 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

of activity, will influence an individual’s exposure to ambient O<sub>3</sub>. Activity patterns vary both among and within individuals, resulting in corresponding variations in exposure across a population and over time” (internal citations omitted).

<sup>48</sup> 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<sub>3</sub> concentrations at and above specific benchmarks levels. As discussed below, these benchmark levels represent exposure concentrations at which O<sub>3</sub>-induced health effects are known to occur, or can reasonably be anticipated to occur, in some individuals.

<sup>44</sup> In addition, because epidemiology-based risk estimates use “area-wide” average O<sub>3</sub> concentrations, calculated by averaging concentrations across multiple monitors in urban case study areas (section 3.2.3.2 below), risk estimates on a given day depend on the daily balance between increasing and decreasing O<sub>3</sub> concentrations at individual monitors.

<sup>45</sup> This was the case for all of the urban study areas evaluated, with the exception of New York

study areas)<sup>49</sup> (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<sub>3</sub> 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 of the proposal (79 FR 75272 to 75273) summarizes key results from the exposure assessment. This table is reprinted below.

**TABLE 1—SUMMARY OF ESTIMATED EXPOSURES OF CONCERN IN ALL SCHOOL-AGE CHILDREN FOR THE CURRENT AND ALTERNATIVE O<sub>3</sub> STANDARDS IN URBAN STUDY AREAS**

Benchmark concentration	Standard level (ppb)	Average % children exposed <sup>50</sup>	Average number of children exposed [average number of asthmatic children] <sup>51</sup>	% Children—worst year and worst area
<b>One or more exposures of concern per season</b>				
≥ 80 ppb .....	75	0–0.3 (0.1)	27,000 [3,000]	1.1
	70	0–0.1 (0)	3,700 [300]	0.2
	65	0 (0)	300 [0]	0
	60	0 (0)	100 <sup>52</sup> [0]	0
	75	0.6–3.3 (1.9)	362,000 [40,000]	8.1
≥ 70 ppb .....	70	0.1–1.2 (0.5)	94,000 [10,000]	3.2
	65	0–0.2 (0.1)	14,000 [2,000]	0.5
	60	0 (0)	1,400 [200]	0.1
	75	9.5–17 (12.2)	2,316,000 [246,000]	25.8
≥ 60 ppb .....	70	3.3–10.2 (6.2)	1,176,000 [126,000]	18.9
	65	0–4.2 (2.1)	392,000 [42,000]	9.5
	60	0–1.2 (0.4)	70,000 [8,000]	2.2
	75	0 (0)	600 [100]	0.1
	70	0 (0)	0 [0]	0
≥ 70 ppb .....	65	0 (0)	0 [0]	0
	60	0 (0)	0 [0]	0
	75	0.1–0.6 (0.2)	46,000 [5,000]	2.2
	70	0–0.1 (0)	5,400 [600]	0.4
≥ 60 ppb .....	65	0 (0)	300 [100]	0
	60	0 (0)	0 [0]	0
	75	3.1–7.6 (4.5)	865,000 [93,000]	14.4
	70	0.5–3.5 (1.7)	320,000 [35,000]	9.2
	65	0–0.8 (0.3)	67,000 [7,500]	2.8
	60	0–0.2 (0)	5,100 [700]	0.3

Uncertainties in exposure estimates are summarized in section II.C.2.b of the proposal (79 FR 75273). 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.<sup>53</sup> In addition, not all of these effects will

be adverse. 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.<sup>54</sup> 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<sub>3</sub> exposure concentrations, and less confidence and greater uncertainty as one considers lower exposure concentrations (e.g., U.S. EPA, 2014c,

<sup>49</sup> HREA exposure estimates for all children and asthmatic children are virtually indistinguishable, in terms of the percent estimated to experience exposures of concern (U.S. EPA, 2014a, Chapter 5). Consistent with this, HREA analyses indicate that activity data for people with asthma is generally similar to non-asthmatic populations (U.S. EPA, 2014a, Appendix 5G, Tables 5G2-to 5G–5).

<sup>50</sup> 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). Numbers in parentheses

reflect averages across urban study areas, as well as over the years evaluated in the HREA.

<sup>51</sup> 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).

<sup>52</sup> As discussed in section 4.3.3 of the HREA, the model-based air quality adjustment approach used to estimate exposures and lung function decrements associated with the current and alternative standards was unable to estimate the distribution of

ambient O<sub>3</sub> 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, and the ranges of percentages, reflect all of the urban study areas except New York.

<sup>53</sup> As noted below (II.C.3.a.ii), in the case of asthmatics, responsiveness to O<sub>3</sub> 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.

<sup>54</sup> The exception to this is lung function decrements, as discussed below (and in U.S. EPA, 2014c, section 3.2.3.1).



sections 3.1 and 4.6). 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.

Another important uncertainty is that there is very limited evidence from controlled human exposure studies, which provided the basis for health benchmark concentrations for both exposures of concern and lung function decrements, related to clinical responses in at-risk populations. Compared to the healthy young adults included in the controlled human exposure studies, members of at-risk populations 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<sub>3</sub> concentrations.<sup>55</sup>

There are also uncertainties associated with the exposure modelling. These are described most fully, and their potential impact characterized, in section 5.5.2 of the HREA (U.S. EPA, 2013, pp. 5–72 to 5–79). These include interpretation of activity patterns set forth in diaries which do not typically distinguish the basis for activity patterns and so may reflect averting behavior,<sup>56</sup> and whether the HREA underestimates exposures for groups spending especially large proportion of time being active outdoors during the O<sub>3</sub> season (outdoor workers and especially active children).

c. Quantitative Health Risk Assessments  
 As discussed in section II.C.3 of the proposal (79 FR 75274), for some health endpoints, there is sufficient scientific evidence and information available to support the development of quantitative estimates of O<sub>3</sub>-related health risks. In the current review, for short-term O<sub>3</sub> 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<sub>3</sub> concentrations, the HREA estimates respiratory mortality (U.S. EPA, 2014a).<sup>57</sup> Estimates of O<sub>3</sub>-induced lung function decrements are based on exposure modeling using the MSS model (see section II.1.b.i.(1) above, and 79 FR 75250), combined with exposure-response relationships from controlled human exposure studies (U.S. EPA, 2014a, Chapter 6). Estimates of O<sub>3</sub>-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<sub>3</sub>-associated health risks are estimated for recent air quality and for ambient concentrations adjusted to just meet the current and alternative O<sub>3</sub> standards, based on 2006–2010 air quality and adjusted precursor emissions. The following sections summarize the discussions from the

proposal on the lung function risk assessment (II.A.2.c.i) and the epidemiology-based morbidity and mortality risk assessments (II.A.2.c.ii).

i. Lung Function Risk Assessment

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<sub>1</sub> responses for individuals following short-term exposures to O<sub>3</sub> (McDonnell et al., 2012), reflecting methodological improvements since the last review (II.B.2.a.i (1), above; U.S. EPA, 2014a, section 6.2.4). The impact of the dose threshold is that O<sub>3</sub>-induced FEV<sub>1</sub> decrements result primarily from exposures on days with average ambient O<sub>3</sub> concentrations above about 40 ppb (U.S. EPA, 2014a, section 6.3.1, Figure 6–9).<sup>58</sup>

Table 2 in the proposal (79 FR 75275), and reprinted 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<sub>3</sub>-induced FEV<sub>1</sub> decrements >10, 15, or 20% when air quality was adjusted to just meet the current and alternative 8-hour O<sub>3</sub> standards. Table 2 also presents the numbers of children, including children with asthma, estimated to experience such decrements.

TABLE 2—SUMMARY OF ESTIMATED O<sub>3</sub>-INDUCED LUNG FUNCTION DECREMENTS FOR THE CURRENT AND POTENTIAL ALTERNATIVE O<sub>3</sub> STANDARDS IN URBAN CASE STUDY AREAS

Lung function decrement	Alternative standard level	Average % children <sup>59</sup>	Number of children (5 to 18 years) [number of asthmatic children] <sup>60</sup>	% Children worst year and area
<b>One or more decrements per season</b>				
≥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	<sup>61</sup> 1,404,000 [139,000]	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

<sup>55</sup> “The CASAC further notes that clinical studies do not address sensitive subgroups, such as children with asthma, and that there is a scientific basis to anticipate that the adverse effects for such subgroups are likely to be more significant at 60 ppb than for healthy adults” (Frey 2014a, p. 7).

<sup>56</sup> See EPA 2014a pp. 5–53 to 54 describing EPA’s sensitivity analysis regarding impacts of potential averting behavior for school-age children on the

exposure and lung function decrement estimate, and see also section B.2.a.i below.

<sup>57</sup> Estimates of O<sub>3</sub>-associated respiratory mortality are based on the study by Jerrett *et al.* (2009). This study used seasonal averages of 1-hour daily maximum O<sub>3</sub> concentrations to estimate long-term concentrations.

<sup>58</sup> 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<sub>1</sub> 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).



TABLE 2—SUMMARY OF ESTIMATED O<sub>3</sub>-INDUCED LUNG FUNCTION DECREMENTS FOR THE CURRENT AND POTENTIAL ALTERNATIVE O<sub>3</sub> STANDARDS IN URBAN CASE STUDY AREAS—Continued

Lung function decrement	Alternative standard level	Average % children <sup>59</sup>	Number of children (5 to 18 years) [number of asthmatic children] <sup>60</sup>	% Children worst year and area
<b>Two or more decrements per season</b>				
≥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
≥15% .....	60	2.1–6.4	741,000 [73,000]	7.3
	75	1.7–2.9	391,000 [40,000]	3.8
	70	0.9–2.4	276,000 [28,000]	3.1
≥20% .....	65	0.1–1.8	168,000 [17,000]	2.3
	60	0.2–1.0	101,000 [10,000]	1.4
	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

Uncertainties in estimates of lung function risks are summarized in section II.C.3.a.ii of the proposal (79 FR 75275). In addition to the uncertainties noted for exposure estimates, an uncertainty which impacts lung function 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<sub>3</sub> exposures as healthy 18 year olds (*i.e.*, the youngest age for which controlled human exposure data is generally 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<sub>1</sub> responses similar to those observed in adults (18–35 years old) (U.S. EPA, 2014a, p. 3–10). In

<sup>59</sup> 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.

<sup>60</sup> 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.

<sup>61</sup> 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<sub>3</sub> 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 experiencing decrements, and the ranges of percentages of such children across study areas, reflect all of the urban study areas except New York City. Because of this, in some cases (*i.e.*, when New York City provided the smallest risk estimate), the lower end of the ranges in Table 2 are higher for a standard level of 60 ppb than for a level of 65 ppb.

addition, as discussed in the ISA (U.S. EPA, 2013, section 6.2.1), summer camp studies of school-aged children reported O<sub>3</sub>-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 thus fixes the age term in the model at its highest value, the value for age 18. Notwithstanding the information just summarized supporting this approach, EPA acknowledges the uncertainty involved, and notes that the approach could result in either over- or underestimates of O<sub>3</sub>-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 of O<sub>3</sub>-induced decrements in asthmatics used the exposure-response relationship developed from data collected from healthy individuals. Although the evidence has been mixed (U.S. EPA, 2013, section 6.2.1.1), several studies have reported statistically larger, or a tendency toward larger, O<sub>3</sub>-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 O<sub>3</sub>-induced pulmonary function decrements” (Frey, 2014c, p. 4). To the extent asthmatics experience larger O<sub>3</sub>-induced lung function decrements than the healthy adults used to develop exposure-response relationships, the HREA could underestimate the impacts of O<sub>3</sub> 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, 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<sub>3</sub> increase with severity of asthma (Horstman et al., 1995) and corticosteroid usage does not prevent O<sub>3</sub> effects on lung function decrements or respiratory symptoms in people with asthma (Vagaggini et al., 2001, 2007).

#### ii. Mortality and Morbidity Risk Assessments

As discussed in section II.C.3.b of the proposal (79 FR 75276), the HREA estimates O<sub>3</sub>-associated risks in 12 urban study areas<sup>62</sup> using concentration-response relationships drawn from epidemiologic studies. These concentration-response relationships are based on “area-wide” average O<sub>3</sub> concentrations.<sup>63</sup> The HREA estimates risks for the years 2007 and 2009 in order to provide estimates of risk for a year with generally higher O<sub>3</sub>

<sup>62</sup> The 12 urban areas evaluated are Atlanta, Baltimore, Boston, Cleveland, Denver, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, and St. Louis.

<sup>63</sup> In the epidemiologic studies that provide the health basis for HREA risk assessments, concentration-response relationships are based on daytime O<sub>3</sub> 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<sub>3</sub> concentrations, averaged across monitors, as surrogates for population exposures. In this notice, we refer to these averaged concentrations as “area-wide” O<sub>3</sub> concentrations. Area-wide concentrations are discussed in more detail in section 3.1.4 of the PA (U.S. EPA, 2014c).

concentrations (2007) and a year with generally lower O<sub>3</sub> concentrations (2009) (U.S. EPA, 2014a, section 7.1.1).

In considering the epidemiology-based risk estimates, the proposal focuses on mortality risks associated with short-term O<sub>3</sub> concentrations. The proposal considers estimates of total risk (*i.e.*, based on the full distributions of ambient O<sub>3</sub> concentrations) and estimates of risk associated with O<sub>3</sub> concentrations in the upper portions of ambient distributions. Both estimates are discussed to provide information that considers risk estimates based on concentration-response relationships being linear over the entire distribution of ambient O<sub>3</sub> concentrations, and thus have the greater potential for morbidity and mortality to be affected by changes in relatively low O<sub>3</sub> concentrations, as well as risk estimates that are associated with O<sub>3</sub> concentrations in the upper portions of the ambient distribution, thus focusing on risk from higher O<sub>3</sub> concentrations and placing greater weight on the uncertainty associated with the shapes of concentration-response curves for O<sub>3</sub> concentrations in the lower portions of the distribution. These results for O<sub>3</sub>-associated mortality risk are summarized in Table 3 in the proposal (79 FR 75277).

Important uncertainties in epidemiology-based risk estimates, based on their consideration in the HREA and PA, are discussed in section II.C.3.b.ii of the proposal (79 FR 75277). Compared to estimates of O<sub>3</sub> exposures of concern and estimates of O<sub>3</sub>-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<sub>3</sub> 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<sub>3</sub>, 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).<sup>64,65</sup> 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<sub>x</sub> emissions generally reduces O<sub>3</sub>-associated mortality and morbidity risk estimates in locations and time periods with relatively high ambient O<sub>3</sub> concentrations and increases risk estimates in locations and time periods with relatively low concentrations (II.A, above). When evaluating uncertainties in epidemiologic risk estimates, the PA considered (1) the extent to which the modeled O<sub>3</sub> response to reductions in NO<sub>x</sub> emissions appropriately represents the trends observed in monitored ambient O<sub>3</sub> following actual reductions in NO<sub>x</sub> emissions, (2) the extent to which the O<sub>3</sub> response to reductions in precursor emissions could differ with emissions reduction strategies that are different from those used in HREA to generate risk estimates, and (3) 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. The first two of these issues are discussed in section II.A.2.c above. The third issue is discussed below.

The HREA conducted national air quality modeling analyses that estimated the proportion of the U.S. population living in locations where seasonal averages of daily O<sub>3</sub> concentrations are estimated to decrease in response to reductions in NO<sub>x</sub> emissions, and the proportion living in locations where such seasonal averages are estimated to increase. Given the close relationship between changes in seasonal averages of daily O<sub>3</sub> 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<sub>x</sub> emissions would be expected to result in decreases in warm season averages of

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).

<sup>65</sup> 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<sub>3</sub> versus repeated occurrences of elevated short-term concentrations.

daily maximum 8-hour ambient O<sub>3</sub> 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<sub>3</sub>-associated mortality and morbidity risks that would be experienced across the U.S. population as a whole upon reducing NO<sub>x</sub> emissions (U.S. EPA, 2014a, section 8.2.3.2).

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<sub>3</sub> concentrations (U.S. EPA, 2014a, Table 7-4).<sup>66</sup> In recognition of the ISA's conclusion that certainty in the shape of O<sub>3</sub> concentration-response functions decreases at low ambient concentrations, the HREA provides estimates of epidemiology-based mortality risks for entire distributions of ambient O<sub>3</sub> concentrations, as well as estimates of total mortality associated with various ambient O<sub>3</sub> concentrations. The PA considers both types of risk estimates, recognizing greater public health concern for adverse O<sub>3</sub>-attributable effects at higher ambient O<sub>3</sub> concentrations (which drive higher exposure concentrations, section 3.2.2 of the PA (U.S. EPA, 2014c)), as compared to lower concentrations.

A related consideration is associated with the public health importance of the increases in relatively low O<sub>3</sub> concentrations following air quality adjustment. There is uncertainty that relates to the assumption that the concentration response function for O<sub>3</sub> is linear, such that total risk estimates are equally influenced by decreasing

<sup>66</sup> A related uncertainty is the existence, or not, of a threshold. The HREA addresses this issue for long-term O<sub>3</sub> by evaluating risks in models that include potential thresholds (II.D.2.c).

<sup>64</sup> 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

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<sub>3</sub> concentrations. To the extent adverse O<sub>3</sub>-attributable effects are more strongly supported for higher ambient concentrations (which, as noted above, are consistently reduced upon air quality adjustment), the impacts on risk estimates of increasing low O<sub>3</sub> concentrations reflect an important source of uncertainty. In addition to the uncertainties discussed above, the proposal also notes uncertainties related to (1) using concentration-response relationships developed for a particular population in a particular location to estimate health risks in different populations and locations; (2) using concentration-response functions from epidemiologic studies reflecting a particular air quality distribution to adjusted air quality necessarily reflecting a different (simulated) air quality distribution; (3) using a national concentration-response function to estimate respiratory mortality associated with long-term O<sub>3</sub>; and (4) unquantified reductions in risk that could be associated with reductions in the ambient concentrations of pollutants other than O<sub>3</sub>, resulting from control of NO<sub>x</sub> (79 FR 75277 to 75279).

#### B. Need for Revision of the Primary Standard

The initial issue to be addressed in the current review of the primary O<sub>3</sub> standard is whether, in view of the advances in scientific knowledge and additional information, it is appropriate to revise the existing standard. This section presents the Administrator's final decision on whether it is "appropriate" to revise the current standard within the meaning of section 109 (d)(1) of the CAA. Section II.B.1 contains a summary discussion of the basis for the proposed conclusions on the adequacy of the primary standard. Section II.B.2 discusses comments received on the adequacy of the primary standard. Section II.B.3 presents the Administrator's final conclusions on the adequacy of the current primary standard.

##### 1. Basis for Proposed Decision

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 in sections II.A to II.C (79 FR 75246–75279) of the proposal and section II.A above.

In developing conclusions on the adequacy of the current primary O<sub>3</sub> 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); see also *American Farm Bureau Federation*, 559 F. 3d at 516, 521 ("[a]lthough not required by the statute, in practice EPA staff also develop a Staff Paper, which discusses the information in the Criteria Document that is most relevant to the policy judgments the EPA makes when it sets the NAAQS"). The PA's evidence-based and exposure-/risk-based considerations and conclusions are briefly summarized below in sections II.B.1.a (evidence-based considerations), II.B.1.b (exposure- and risk-based considerations), and II.B.1.c (PA conclusions on the current standard). Section II.B.1.d summarizes CASAC advice to the Administrator and public commenter views on the current standard. Section II.B.1.e presents a summary of 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.

##### a. Evidence-Based Considerations From the PA

In considering the available scientific evidence, the PA evaluates the O<sub>3</sub> concentrations in health effects studies (U.S. EPA, 2014c, section 3.1.4).

Specifically, the PA characterizes the extent to which health effects have been reported for the O<sub>3</sub> exposure concentrations evaluated in controlled human exposure studies, and effects occurring over the distributions of ambient O<sub>3</sub> 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 in the proposal (79 FR 75279–75287). The PA's considerations are summarized briefly below for controlled human exposure, epidemiologic panel studies, and epidemiologic population-based studies.

Section II.D.1.a of the proposal discusses the PA's consideration of the evidence from controlled human exposure and panel studies. This evidence is assessed in section 6.2 of the ISA (U.S. EPA, 2013) and is summarized in section 3.1.2 of the PA (U.S. EPA, 2014c). A large number of controlled human exposure studies have reported lung function decrements, respiratory symptoms, air inflammation, airway hyperresponsiveness, and/or impaired lung host defense in young, healthy adults engaged in moderate quasi-continuous exertion, following 6.6-hour O<sub>3</sub> exposures. These studies have consistently reported such effects following exposures to O<sub>3</sub> concentrations of 80 ppb or greater. In addition to lung function decrements, available studies have evaluated respiratory symptoms or airway inflammation following exposures to O<sub>3</sub> concentrations below 75 ppb. Table 3–1 in the PA highlights the group mean results of individual controlled human exposure studies that evaluated exposures to O<sub>3</sub> concentrations below 75 ppb. These studies observe the combination of lung function decrements and respiratory symptoms following exposures to O<sub>3</sub> concentrations as low as 72 ppb, and lung function decrements and airway inflammation following exposures to O<sub>3</sub> concentrations as low as 60 ppb (based on group means).

Based on this evidence, the PA notes that controlled human exposure studies have reported a variety of respiratory effects in young, healthy adults following exposures to a wide range of O<sub>3</sub> concentrations for 6.6 hours, including exposures to concentrations below 75 ppb. In particular, the PA further notes that a recent controlled human exposure study reported the combination of lung function decrements and respiratory symptoms in healthy adults engaged in quasi-

continuous, moderate exertion following 6.6 hour exposures to 72 ppb O<sub>3</sub>, a combination of effects that have been classified as adverse based on ATS guidelines for adversity (ATS, 2000a). In addition, a recent study has also reported lung function decrements and pulmonary inflammation following exposure to 60 ppb O<sub>3</sub>. Sixty ppb is the lowest exposure concentration for which inflammation has been evaluated and reported to occur, and corresponds to the lowest exposure concentration demonstrated to result in lung function decrements large enough to be judged an abnormal response by ATS (ATS, 2000b). The PA also notes, and CASAC agreed, that these controlled human exposure studies were conducted in healthy adults, while at-risk groups (e.g., children, people with asthma) could experience larger and/or more serious effects. Therefore, the PA concludes that the evidence from controlled human exposure studies provide support that the respiratory effects experienced following exposures to O<sub>3</sub> concentrations lower than 75 ppb would be adverse in some individuals, particularly if experienced by members of at-risk populations (e.g., people with asthma, children).

The PA also notes consistent results in some panel studies of O<sub>3</sub>-associated lung function decrements. In particular, the PA notes that epidemiologic panel studies in children and adults consistently indicate O<sub>3</sub>-associated lung function decrements when on-site, ambient monitored concentrations were below 75 ppb (although the evidence becomes less consistent at low O<sub>3</sub> concentrations, and the averaging periods involved ranged from 10 minutes to 12 hours (U.S. EPA, 2014c, section 3.2.4.2)).

Section II.D.1.b of the proposal summarizes the PA's analyses of monitored O<sub>3</sub> concentrations in locations of epidemiologic studies. While the majority of the epidemiologic study areas evaluated would have violated the current standard during study periods, the PA makes the following observations with regard to health effect associations at O<sub>3</sub> concentrations likely to have met the current standard:

(1) A single-city study reported positive and statistically significant associations with asthma emergency department visits in children and adults in Seattle, a location that would have met the current standard over the entire study period (Mar and Koenig, 2009).

(2) Additional single-city studies support associations with respiratory morbidity at relatively low ambient O<sub>3</sub> concentrations, including when

virtually all monitored concentrations were below the level of the current standard (Silverman and Ito, 2010; Strickland et al., 2010).

(3) Canadian multicity studies reported positive and statistically significant associations with respiratory morbidity or mortality when the majority of study cities, though not all study cities, would have met the current standard over the study period in each of these studies (Cakmak et al., 2006; Dales et al., 2006; Katsouyanni et al., 2009; Stieb et al., 2009).

(4) A U.S. multicity study reported positive and statistically significant associations with mortality when ambient O<sub>3</sub> concentrations were restricted to those likely to have met the current O<sub>3</sub> standard (Bell et al., 2006).

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 section II.D.1.b.iii of the proposal. Briefly, they include the following: (1) Uncertainty in conclusions about the extent to which multicity effect estimates reflect associations with air quality meeting the current standard, versus air quality violating that standard; (2) uncertainty regarding the potential for thresholds to exist, given that regional heterogeneity in O<sub>3</sub> health effect associations could obscure the presence of thresholds, should they exist; (3) uncertainty in the extent to which the PA appropriately recreated the air quality analyses in the published study by Bell et al. (2006); and (4) uncertainty in the extent to which reported health effects are caused by exposures to O<sub>3</sub> itself, as opposed to other factors such as co-occurring pollutants or pollutant mixtures, particularly at low ambient O<sub>3</sub> concentrations.<sup>67</sup>

In considering the analyses of monitored O<sub>3</sub> air quality in locations of epidemiologic studies, as well as the important uncertainties in these analyses, the PA concludes that these analyses provide support for the occurrence of morbidity and mortality associated with short-term ambient O<sub>3</sub> concentrations likely to meet the current O<sub>3</sub> standard.<sup>68</sup> In considering the

<sup>67</sup> As noted above (section II.A.1.B.i), the ISA concludes that studies that examined the potential confounding effects of copollutants found that O<sub>3</sub> effect estimates remained relatively robust upon the inclusion of PM and gaseous pollutants in two-pollutant models (U.S. EPA, 2013, section 6.2.7.5).

<sup>68</sup> Unlike for the studies of short-term O<sub>3</sub>, the available U.S. and Canadian epidemiologic studies evaluating long-term ambient O<sub>3</sub> concentration metrics have not been conducted in locations likely to have met the current 8-hour O<sub>3</sub> standard during the study period, and have not reported concentration-response functions that indicate

evidence as a whole, the PA concludes that (1) controlled human exposure studies provide strong support for the occurrence of adverse respiratory effects following exposures to O<sub>3</sub> concentrations below the level of the current standard and (2) epidemiologic studies provide support for the occurrence of adverse respiratory effects and mortality under air quality conditions that would meet the current standard.

#### b. Exposure- and Risk-Based Considerations in the PA

In order to further inform judgments about the potential public health implications of the current O<sub>3</sub> 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 brief summaries of key results and uncertainties, are provided in section II.A.2 above. Section II.D.2 of the proposal summarizes key observations from the PA related to the adequacy of the current O<sub>3</sub> NAAQS, based on consideration of the HREA exposure assessment, lung function risk assessment, and mortality/morbidity risk assessments (79 FR 75283).

Section II.D.2.a of the proposal summarizes key observations from the PA regarding estimates of O<sub>3</sub> exposures of concern (79 FR 75283). Given the evidence for respiratory effects from controlled human exposure studies, the PA considers the extent to which the current standard would be estimated to protect at-risk populations against exposures of concern to O<sub>3</sub> 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-

confidence in health effect associations at O<sub>3</sub> concentrations meeting the current standard (U.S. EPA, 2014c, section 3.1.4.3).

related effects have been observed in clinical studies of healthy individuals.

For exposures of concern at or above 60 ppb, the proposal 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<sub>3</sub> season. Of these children, almost 250,000 are asthmatics.<sup>69</sup>

(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<sub>3</sub> 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).

(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<sub>3</sub> exposure concentrations at or above 70 ppb during a single O<sub>3</sub> 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 exposures of concern to O<sub>3</sub> concentrations at or above 70 ppb.

(3) In the worst-case location and year, the current standard is estimated to allow approximately 8% of children to experience one or more exposures of concern at or above 70 ppb, and 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.

Uncertainties in exposure estimates are summarized in section II.C.2.b of the proposal (79 FR 75273), and discussed more fully in the HREA (U.S. EPA, 2014a, section 5.5.2) and the PA (U.S. EPA, 2014c, section 3.2.2). Key uncertainties include the variability in responsiveness following O<sub>3</sub> exposures, resulting in only a subset of exposed individuals experiencing health effects, adverse or otherwise, and the limited evidence from controlled human exposure studies conducted in at-risk populations. In addition, there are a number of uncertainties in the exposure modelling approach used in the HREA, contributing to overall uncertainty in exposure estimates.

Section II.D.2.b of the proposal summarizes key observations from the PA regarding the estimated risk of O<sub>3</sub>-induced lung function decrements (79 FR 75283 to 75284). 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 one or more, and two or more, moderate (*i.e.*, FEV<sub>1</sub> decrements  $\geq 10\%$  and  $\geq 15\%$ ) and large (*i.e.*, FEV<sub>1</sub> decrements  $\geq 20\%$ ) lung function decrements. As discussed in section 3.1.3 of the PA (U.S. EPA, 2014c), 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.

With regard to decrements  $\geq 10\%$ , 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 14 to 19% of children in urban study areas to experience one or more lung function decrements  $\geq 10\%$ . Summing across

urban study areas, this corresponds to approximately 3 million children experiencing 15 million O<sub>3</sub>-induced lung function decrements  $\geq 10\%$  during a single O<sub>3</sub> 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<sub>3</sub>-induced lung function decrements  $\geq 10\%$ . 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<sub>3</sub>-induced lung function decrements greater than 10% during a single O<sub>3</sub> 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  $\geq 10\%$ , and approximately 10 to 14% to experience two or more O<sub>3</sub>-induced lung function decrements  $\geq 10\%$ . With regard to decrements  $\geq 15\%$ , 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  $\leq 15\%$ . 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<sub>3</sub>-induced lung function decrement  $\leq 15\%$  during a single O<sub>3</sub> 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<sub>3</sub>-induced lung function decrements  $\leq 15\%$ .

(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  $\leq 15\%$ , and approximately 2 to 4% to experience two or more O<sub>3</sub>-induced lung function decrements  $\leq 15\%$ .

With regard to decrements  $\leq 20\%$ , 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  $\geq 20\%$ . Summing across

<sup>69</sup> As discussed in section II.C.2.b of the proposal, 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.

urban study areas, this corresponds to approximately 300,000 children (including approximately 30,000 asthmatic children) estimated to experience at least one O<sub>3</sub>-induced lung function decrement  $\geq 20\%$  during a single O<sub>3</sub> 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<sub>3</sub>-induced lung function decrements  $\geq 20\%$ .

(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  $\geq 20\%$ , and less than 2% to experience two or more O<sub>3</sub>-induced lung function decrements  $\geq 20\%$ .

Uncertainties in lung function risk estimates are summarized in section II.C.3.a of the proposal, and discussed more fully in the HREA (U.S. EPA, 2014a, section 6.5) and the PA (U.S. EPA, 2014c, section 3.2.3.1). In addition to the uncertainties noted above for exposure estimates, the key uncertainties associated with estimates of O<sub>3</sub>-induced lung function decrements include the paucity of exposure-response information in children and in people with asthma.

Section II.D.2.c of the proposal summarizes key observations from the PA regarding risk estimates of O<sub>3</sub>-associated mortality and morbidity (79 FR 75284 to 75285). With regard to total mortality or morbidity associated with short-term O<sub>3</sub>, 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<sub>3</sub>-associated risks), 10 of 12 urban study areas exhibited either decreases or virtually no change in estimates of the number of O<sub>3</sub>-associated deaths (U.S. EPA, 2014a, Appendix 7B). Increases were estimated in two of the urban

study areas (Houston, Los Angeles)<sup>70</sup> (U.S. EPA, 2014a, Appendix 7B).<sup>71</sup>

(2) In focusing on total risk, the current standard is estimated to allow thousands of O<sub>3</sub>-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  $\leq 40, 60$  ppb), the current standard is estimated to allow hundreds to thousands of O<sub>3</sub>-associated deaths per year in the urban study areas.

(3) The current standard is estimated to allow tens to thousands of O<sub>3</sub>-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<sub>3</sub>, 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<sub>3</sub>-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<sub>3</sub> concentrations could potentially be considerably lower (*i.e.*,

<sup>70</sup> As discussed above (II.C.1), in locations and time periods when NO<sub>x</sub> is predominantly contributing to O<sub>3</sub> formation (*e.g.*, downwind of important NO<sub>x</sub> sources, where the highest O<sub>3</sub> concentrations often occur), model-based adjustment to the current and alternative standards decreases estimated ambient O<sub>3</sub> concentrations compared to recent monitored concentrations (U.S. EPA, 2014a, section 4.3.3.2). In contrast, in locations and time periods when NO<sub>x</sub> is predominantly contributing to O<sub>3</sub> titration (*e.g.*, in urban centers with high concentrations of NO<sub>x</sub> emissions, where ambient O<sub>3</sub> concentrations are often suppressed and are thus relatively low), model-based adjustment increases ambient O<sub>3</sub> 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<sub>3</sub> concentrations and increases in low O<sub>3</sub> 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 fourth-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).

<sup>71</sup> For the 2009 adjusted year (*i.e.*, the year with generally lower O<sub>3</sub> 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.

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).<sup>72</sup>

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<sub>3</sub> concentrations (U.S. EPA, 2014a, section 9.6).

Uncertainty in the shape of concentration-response functions at lower O<sub>3</sub> concentrations is particularly important to interpreting risk estimates given the approach used to adjust air quality to just meet the current standard, and potential alternative standards, and the resulting compression in the air quality distributions (*i.e.*, decreasing high concentrations and increasing low concentrations) (II.A.2.a, above). Total risk estimates in the HREA are based on the assumption that the concentration response function for O<sub>3</sub> is linear, such that total risk estimates are equally influenced by decreasing high concentrations and increasing low concentrations, when the increases and decreases are of equal magnitude. However, consistent with the PA’s consideration of risk estimates, in the proposal the Administrator notes that the overall body of evidence provides stronger support for the occurrence of

<sup>72</sup> Risk estimates for respiratory mortality associated with long-term O<sub>3</sub> 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<sub>3</sub> concentrations ranged from 33 to 104 ppb, there was no statistical deviation from a linear concentration-response relationship between O<sub>3</sub> and respiratory mortality across 96 U.S. cities (U.S. EPA, 2013, section 7.7). However, the authors reported “limited evidence” for an effect threshold at an O<sub>3</sub> 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.”

O<sub>3</sub>-attributable health effects following exposures to O<sub>3</sub> concentrations corresponding to the upper ends of typical ambient distributions (II.E.4.d of the proposal). In addition, 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<sub>3</sub> concentrations. Therefore, to the extent adverse O<sub>3</sub>-attributable effects are more strongly supported for higher ambient concentrations (which, as noted above, are consistently reduced upon air quality adjustment), the PA notes that the impacts on risk estimates of increasing low O<sub>3</sub> concentrations reflect an important source of uncertainty.

#### c. PA Conclusions on the Current Standard

Section II.D.3 of the proposal summarizes the PA conclusions on the adequacy of the existing primary O<sub>3</sub> standard (79 FR 75285). As an initial matter, the PA concludes that reducing precursor emissions to achieve O<sub>3</sub> 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<sub>3</sub> concentrations commonly found in the ambient air and (2) estimates indicating decreased occurrences of O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub>-induced lung function decrements reflect the consistent decreases in the highest O<sub>3</sub>

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<sub>3</sub> exposures and O<sub>3</sub>-induced lung function risks upon meeting the current standard.

The PA further concludes that support for this initial conclusion is also provided by estimates of O<sub>3</sub>-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 are based on the assumption that concentration-response relationships are linear over entire distributions of ambient O<sub>3</sub> concentrations, an assumption which has uncertainties that complicate interpretation of these estimates (II.A.2.c.ii). However, risk estimates for effects associated with short- and long-term O<sub>3</sub> exposures, combined with the HREA's national analysis of O<sub>3</sub> responsiveness to reductions in precursor emissions and the consistent reductions estimated for the highest ambient O<sub>3</sub> concentrations, suggest that O<sub>3</sub>-associated mortality and morbidity would be expected to decrease nationwide following reductions in precursor emissions to meet the current O<sub>3</sub> standard.

After reaching the initial conclusion that meeting the current primary O<sub>3</sub> 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 current standard. In considering the available scientific evidence, exposure/risk information, advice from CASAC (II.B.1.d, 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<sub>3</sub> 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<sub>3</sub> standard to provide increased public health protection.

#### d. CASAC Advice

Section II.D.4 of the proposal summarizes CASAC advice regarding the adequacy of the existing primary O<sub>3</sub> standard. Following the 2008 decision to revise the primary O<sub>3</sub> 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.D), 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<sub>3</sub> 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<sub>3</sub> 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). In 2010, in response to the EPA's solicitation of advice on the EPA's



proposed rulemaking as part of the reconsideration, CASAC again stated that the current standard should be revised to provide additional protection to the public health (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 the 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<sub>3</sub> 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<sub>3</sub> 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.<sup>73</sup>

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<sub>1</sub> 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 60 ppb exposures, CASAC noted 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). The 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).

In their advice, CASAC also took note of estimates of O<sub>3</sub> exposures of concern and the risk of O<sub>3</sub>-induced lung function decrements. With regard to the benchmark concentrations used in estimating exposures of concern, 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.

With regard to lung function risk estimates, CASAC concluded that “estimation of FEV<sub>1</sub> decrements of ≥15% is appropriate as a scientifically relevant surrogate for adverse health outcomes in active healthy adults, whereas an FEV<sub>1</sub> 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<sub>3</sub>-induced pulmonary function decrements” (Frey, 2014c, p. 4).

Although CASAC judged that controlled human exposure studies of respiratory effects provide the strongest

<sup>73</sup> CASAC provided similar advice in their letter to the Administrator on the HREA, 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).



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) and 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).

#### e. Administrator’s Proposed Decision

Section II.D.5 in the proposal (79 FR 75287–75291) discusses the Administrator’s proposed conclusions related to the adequacy of the public health protection provided by the current primary O<sub>3</sub> standard, resulting in her proposed decision to revise that standard. These proposed conclusions and her proposed decision, summarized below, were based on the Administrator’s consideration of the available scientific evidence, exposure/risk information, the comments and advice of CASAC, and public input that had been received by the time of proposal.

As an initial matter, the Administrator concluded that reducing precursor emissions to achieve O<sub>3</sub> concentrations that meet the current primary O<sub>3</sub> standard will provide important improvements in public health protection, compared to recent air quality. In reaching this initial conclusion, she noted the discussion in section 3.4 of the PA (U.S. EPA, 2014c). In particular, the Administrator noted 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<sub>3</sub> concentrations commonly measured in the ambient air and (2) estimates indicating decreased occurrences of O<sub>3</sub> exposures of concern and decreased O<sub>3</sub>-associated health risks upon meeting the current standard, compared to recent air quality. Thus, she concluded that it would not be appropriate in this review to consider a standard that is less protective than the current standard.<sup>74</sup>

<sup>74</sup> Although the Administrator noted that reductions in O<sub>3</sub> precursor emissions (e.g., NO<sub>x</sub>; VOC) to achieve O<sub>3</sub> concentrations that meet the current standard could also increase public health protection by reducing the ambient concentrations of pollutants other than O<sub>3</sub> (e.g., PM<sub>2.5</sub>, NO<sub>2</sub>), we did not quantitatively analyze these effects, consistent with CASAC advice (Frey, 2014a, p.10). However, the Administrator is not setting the standard to address risks from pollutants other than O<sub>3</sub>.

After reaching the initial conclusion that meeting the current primary O<sub>3</sub> 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 considered the adequacy of the public health protection that is provided by the current standard. In doing so, the Administrator first noted that studies evaluated since the completion of the 2006 AQCD support and expand upon the strong body of evidence that, in the last review, indicated a causal relationship between short-term O<sub>3</sub> exposures and respiratory health effects, the strongest determination 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<sub>3</sub> 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. The Administrator further noted that recent animal toxicology studies support descriptions of modes of action for these respiratory effects and provide support for biological plausibility for the role of O<sub>3</sub> in reported effects. With regard to mode of action, evidence indicates that antioxidant capacity may modify the risk of respiratory morbidity associated with O<sub>3</sub> exposure, and that the inherent capacity to quench (based on individual antioxidant capacity) can be overwhelmed, especially with exposure to elevated concentrations of O<sub>3</sub>. 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<sub>3</sub>-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 noted that evidence for adverse respiratory health effects attributable to long-term<sup>75</sup> O<sub>3</sub>

<sup>75</sup> Based on the exposure surrogates used in recent epidemiologic studies of long-term O<sub>3</sub> exposure, it is not possible to distinguish between

exposures is much stronger than in previous reviews, and noted the ISA’s conclusion that there is “likely to be” a causal relationship between such O<sub>3</sub> exposures and adverse respiratory health effects (the second strongest causality determination). She noted that 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<sub>3</sub> exposures and measures of respiratory morbidity and mortality. New evidence supports associations between long-term O<sub>3</sub> exposures and the development of asthma in children, with several studies reporting interactions between genetic variants and such O<sub>3</sub> exposures. Studies also report associations between long-term O<sub>3</sub> exposures and asthma prevalence, asthma severity and control, respiratory symptoms among asthmatics, and respiratory mortality.

In considering the O<sub>3</sub> exposure concentrations reported to elicit respiratory effects, the Administrator agreed 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<sub>3</sub> concentrations. In particular, she noted that the effects reported in controlled human exposure studies are due solely to O<sub>3</sub> exposures, and interpretation of study results is not complicated by the presence of co-occurring pollutants or pollutant mixtures.

In considering the evidence from controlled human exposure studies, the Administrator first noted that these studies have reported a variety of respiratory effects in healthy adults following exposures to O<sub>3</sub> concentrations of 60, 72, 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<sub>3</sub> or higher, with most exposure studies conducted at these higher concentrations. She further noted that recent evidence includes controlled human exposure studies reporting the combination of lung function decrements and respiratory symptoms in healthy adults engaged in quasi-continuous, moderate exertion following 6.6 hour exposures to concentrations as low as 72 ppb, and lung function decrements and

the impacts of long-term O<sub>3</sub> exposure and exposure to repeated short-term peaks over an O<sub>3</sub> season.

pulmonary inflammation following exposures to O<sub>3</sub> concentrations as low as 60 ppb. As discussed below, compared to the evidence available in the last review, the Administrator viewed these studies as having strengthened support for the occurrence of abnormal and adverse respiratory effects attributable to short-term exposures to O<sub>3</sub> concentrations below the level of the current standard. The Administrator stated that such exposures to O<sub>3</sub> 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<sub>3</sub> 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<sub>1</sub> 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<sub>3</sub>, 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<sub>3</sub> (*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<sub>3</sub> standard placed a large amount of weight on the results of controlled human exposure studies. In particular, given the combination of lung function decrements and respiratory symptoms

following 6.6-hour exposures to O<sub>3</sub> concentrations as low as 72 ppb, and given CASAC advice regarding effects at 72 ppb, along with ATS adversity criteria, she concluded that the evidence in this review supports the occurrence of adverse respiratory effects following exposures to O<sub>3</sub> concentrations lower than the level of the current standard.<sup>76</sup> As discussed below, the Administrator further considered information from the broader body of controlled human exposure studies within the context of quantitative estimates of exposures of concern and O<sub>3</sub>-induced FEV<sub>1</sub> decrements.

While putting less weight on information from epidemiologic studies than on information from controlled human exposure studies, the Administrator also considered what the available epidemiologic evidence indicates with regard to the adequacy of the public health protection provided by the current primary O<sub>3</sub> standard. She noted that recent epidemiologic studies provide support, beyond that available in the last review, for associations between short-term O<sub>3</sub> 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 considered the extent to which available studies support the occurrence of O<sub>3</sub> health effect associations with air quality likely to be allowed by the current standard. Most of the epidemiologic studies considered by the Administrator were conducted in locations likely to have violated the current standard over at least part of the study period. However, she noted three U.S. single-city studies that support the occurrence of O<sub>3</sub>-associated hospital admissions or emergency department visits at ambient O<sub>3</sub> concentrations below the level of the current standard, or when virtually all monitored concentrations were below the level of the current standard (Mar and Koenig, 2009; Silverman and Ito, 2010; Strickland et al., 2010) (section II.D.1 of the proposal). While the Administrator acknowledged greater uncertainty in interpreting air quality for multicity

studies, she noted that O<sub>3</sub> associations with respiratory morbidity or mortality have been reported when the majority of study locations (though not all study locations) would likely have met the current O<sub>3</sub> standard. When taken together, the Administrator reached the initial conclusion at proposal that single-city epidemiologic studies and associated air quality information support the occurrence of O<sub>3</sub>-associated hospital admissions and emergency department visits for ambient O<sub>3</sub> 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, including mortality.

Beyond her consideration of the scientific evidence, the Administrator also considered the results of the HREA exposure and risk analyses in reaching initial conclusions regarding the adequacy of the current primary O<sub>3</sub> standard. In doing so, as noted above, she focused primarily on exposure and risk estimates based on information from controlled human exposure studies (*i.e.*, exposures of concern and O<sub>3</sub>-induced lung function decrements) and placed relatively less weight on epidemiologic-based risk estimates.

With regard to estimates of exposures of concern, the Administrator considered the extent to which the current standard provides protection against exposures to O<sub>3</sub> concentrations at or above 60, 70, and 80 ppb. Consistent with CASAC advice (Frey, 2014c), the Administrator focused on children in these analyses of O<sub>3</sub> exposures, noting that estimates for all children and asthmatic children are virtually indistinguishable, in terms of the percent estimated to experience exposures of concern.<sup>77</sup> Though she focused on children, she also recognized that exposures to O<sub>3</sub> 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 of the proposal), 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 recognized that the exposure patterns for children across years, urban study areas, and air

<sup>76</sup> This CASAC advice and ATS recommendations are discussed in more detail in section II.C.4 below (see also II.A.1.c, above).

<sup>77</sup> As noted above, HREA analyses indicate that activity data for asthmatics is generally similar to non-asthmatics (U.S. EPA, 2014a, Appendix 5G, Tables 5G2-to 5G-5).

quality scenarios are indicative of the exposure patterns in a broader group of at-risk populations that also includes asthmatic adults and older adults.

She further noted 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, she became increasingly concerned about the potential for adverse responses as the number of occurrences increases (61 FR 75122).<sup>78</sup> In particular, she noted 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, 2013, section 6.2.3). Thus, the Administrator noted that the types of respiratory effects shown to occur in some individuals following exposures to O<sub>3</sub> concentrations from 60 to 80 ppb, particularly if experienced repeatedly, provide a mode of action by which O<sub>3</sub> may cause other more serious effects (e.g., asthma exacerbations). Therefore, the Administrator placed 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 considered estimates of one or more, particularly for the 70 and 80 ppb benchmarks.<sup>79</sup>

As illustrated in Table 1 (above), the Administrator noted that if the 15 urban study areas evaluated in the HREA were to just meet the current O<sub>3</sub> 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<sub>3</sub> concentrations at or above 60 ppb<sup>80</sup> (based on estimates averaged over the years of analysis). To provide some perspective on these percentages, the Administrator noted 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 noted 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 of the proposal, the Administrator was less concerned about single occurrences of exposures of concern, she noted that even single occurrences can cause adverse effects in some people, particularly for the 70 and 80 ppb benchmarks. Therefore, she also considered 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<sub>3</sub> 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<sub>3</sub> concentrations at or above 70 ppb and approximately 10 to 17% would be estimated to experience one or more exposures of concern to O<sub>3</sub> concentrations at or above 60 ppb. In the worst-case year and location, the Administrator noted 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 considered HREA estimates of the

occurrence of O<sub>3</sub>-induced lung function decrements. In doing so, she particularly noted CASAC advice that “estimation of FEV<sub>1</sub> decrements of ≥15% is appropriate as a scientifically relevant surrogate for adverse health outcomes in active healthy adults, whereas an FEV<sub>1</sub> decrement of ≥10% is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease” (Frey, 2014c, p. 3). While these surrogates provide perspective on the potential for the occurrence of adverse respiratory effects following O<sub>3</sub> exposures, the Administrator agreed 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 (citing to 61 FR 65722–3) (Dec, 13, 1996). Therefore, in the proposal the Administrator expressed increasing concern about the potential for adversity as the frequency of occurrences increased and, as a result, she focused primarily on estimates of two or more O<sub>3</sub>-induced FEV<sub>1</sub> decrements (i.e., as a surrogate for repeated exposures).

When averaged over the years evaluated in the HREA, the Administrator noted 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<sub>3</sub>-induced lung function decrements ≥15%, and to allow about 8 to 12% of children (corresponding to about 180,000 asthmatic children) to experience two or more O<sub>3</sub>-induced lung function decrements ≥10%. Nationally, larger numbers of children would be expected to experience such O<sub>3</sub>-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).<sup>81</sup>

<sup>81</sup> As discussed below (II.C.4), in her consideration of potential alternative standard levels, the Administrator placed less weight on estimates of the risk of O<sub>3</sub>-induced FEV<sub>1</sub> decrements. In doing so, she particularly noted that, unlike exposures of concern, the variability in lung

<sup>78</sup> The Administrator noted that 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<sub>3</sub>-induced FEV<sub>1</sub> decrements, as discussed below), the number of those experiencing exposures of concern who will experience adverse effects cannot be reliably quantified.

<sup>79</sup> The Administrator's considerations related to estimated O<sub>3</sub> exposures of concern, including her views on estimates of two or more and one or more such exposures, are discussed in more detail within the context of her consideration of public comments on the level of the revised standard and her final decision on level (II.C.4.b and II.C.4.c, below).

<sup>80</sup> Almost no children in those areas would be estimated to experience two or more exposures of concern at or above 80 ppb.

In further considering the HREA results, the Administrator considered the epidemiology-based risk estimates. Compared to the weight given to HREA estimates of exposures of concern and lung function risks, she placed relatively less weight on epidemiology-based risk estimates. Consistent with the conclusions in the PA, her determination to attach less weight to the epidemiologic-based risk estimates reflected 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<sub>3</sub> concentrations in the lower portions of ambient distributions (U.S. EPA, 2014a, section 9.6) (section II.D.2 of the proposal).

The Administrator focused on estimates of total mortality risk associated with short-term O<sub>3</sub> exposures.<sup>82</sup> Given the decreasing certainty in the shape of concentration-response functions for area-wide O<sub>3</sub> concentrations at the lower ends of warm season distributions (U.S. EPA, 2013, section 2.5.4.4), the Administrator focused on estimates of risk associated with O<sub>3</sub> concentrations in the upper portions of ambient distributions. Even when considering only area-wide O<sub>3</sub> concentrations from these upper portions of seasonal distributions, the Administrator noted that the current standard is estimated to allow hundreds to thousands of O<sub>3</sub>-associated deaths per year in urban study areas (79 FR 75291 citing to section II.C.3 of the proposal).

In addition to the evidence and exposure/risk information discussed above, the Administrator took note of the CASAC advice in the current review and in the 2010 proposed

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 noted her confidence in the lung function risk estimates themselves, she viewed 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.

<sup>82</sup> In doing so, she concluded that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O<sub>3</sub> 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 identification of a potential threshold in the concentration-response function (U.S. EPA, 2014a, section 9.6) (section II.D.2 of the proposal). 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).

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).

In consideration of all of the above, the Administrator proposed that the current primary O<sub>3</sub> standard is not adequate to protect public health, and that it should be revised to provide increased public health protection. This proposed decision was 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 noted that (1) controlled human exposure studies provide support for the occurrence of adverse respiratory effects following exposures to O<sub>3</sub> 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 limited support for this conclusion for a broader range of effects (*i.e.*, including mortality). In addition, based on the analyses in the HREA, the Administrator concluded 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 reached 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.

## 2. Comments on the Need for Revision

The EPA received a large number of comments, more than 430,000 comments, on the proposed decision to revise the current primary O<sub>3</sub> standard. These comments generally fell into one

of two broad groups that expressed sharply divergent views.

Many commenters asserted that the current primary O<sub>3</sub> standard is not sufficient to protect public health, especially the health of sensitive groups, with an adequate margin of safety. These commenters agreed with the EPA’s proposed decision to revise the current standard to increase public health protection. Among those calling for revisions to the current primary standard were medical groups (*e.g.*, American Academy of Pediatrics (AAP), American Medical Association, American Lung Association (ALA), American Thoracic Society, American Heart Association, and the American College of Occupational and Environmental Medicine); national, state, and local public health and environmental organizations (*e.g.*, the National Association of County and City Health Officials, American Public Health Association, Physicians for Social Responsibility, Sierra Club, Natural Resources Defense Council, Environmental Defense Fund, Center for Biological Diversity, and Earthjustice); the majority of state and local air pollution control authorities that submitted comments (*e.g.*, agencies from California Air Resources Board and Office of Environmental Health Hazard Assessment, Connecticut, Delaware, Iowa, Illinois, Maryland, Minnesota, New Hampshire, New York, North Dakota, Oregon, Pennsylvania, Tennessee, and Wisconsin); the National Tribal Air Association; State organizations (*e.g.*, National Association of Clean Air Agencies (NACAA), Northeast States for Coordinated Air Use Management, Ozone Transport Commission). While all of these commenters agreed with the EPA that the current O<sub>3</sub> standard needs to be revised, many supported a more protective standard than proposed by EPA, as discussed in more detail below (II.C.4). Many individual commenters also expressed similar views.

A second group of commenters, representing industry associations, businesses and some state agencies, opposed the proposed decision to revise the current primary O<sub>3</sub> standard, expressing the view that the current standard is adequate to protect public health, including the health of sensitive groups, and to do so with an adequate margin of safety. Industry and business groups expressing this view included the American Petroleum Institute (API), the Alliance of Automobile Manufacturers (AAM), the American Forest and Paper Association, the Dow Chemical Company, the National Association of Manufacturers, the

National Mining Association, the U.S. Chamber of Commerce (in a joint comment with other industry groups), and the Utility Air Regulatory Group (UARG). State environmental agencies opposed to revising the current primary O<sub>3</sub> standard included agencies from Arkansas, Georgia, Louisiana, Kansas, Michigan, Mississippi, Nebraska, North Carolina, Ohio, Texas, Virginia, and West Virginia.

The following sections discuss comments submitted by these and other groups, and the EPA's responses to those comments. Comments dealing with overarching issues that are fundamental to EPA's decision-making methodology are addressed in section II.B.2.a. Comments on the health effects evidence, including evidence from controlled human exposure and epidemiologic studies, are addressed in section II.B.2.b. Comments on human exposure and health risk assessments are addressed in section II.B.2.c. Comments on the appropriate indicator, averaging time, form, or level of a revised primary O<sub>3</sub> standard are addressed below in section II.C. In addition to the comments addressed in this preamble, the EPA has prepared a Response to Comments document that addresses other specific comments related to standard setting, as well as comments on implementation- and/or cost-related factors that the EPA may not consider as part of the basis for decisions on the NAAQS. This document is available for review in the docket for this rulemaking and through the EPA's OAQPS TTN Web site ([http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_index.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html)).

#### a. Overarching Comments

Some commenters maintained that the proposed rule (and by extension the final rule) is fundamentally flawed because it does not quantify, or otherwise define, what level of protection is "requisite" to protect the public health. These commenters asserted that "EPA has not explained how far above zero-risk it believes is appropriate or how close to background is acceptable. EPA has failed to explain how the current standard is inadequate on this specific basis" (e.g., UARG, p. 10). These commenters further maintained that the failure to quantify a requisite level of protection "drastically reduces the value of public participation" since "the public does not understand what is driving EPA's decision" (e.g., UARG, p. 11).

The EPA disagrees with these comments and notes that industry petitioners made virtually the same argument before the D.C. Circuit in *ATA*

*III*, on remand from the Supreme Court, arguing that unless EPA identifies and quantifies a degree of acceptable risk, it is impossible to determine if a NAAQS is requisite (i.e., neither too stringent or insufficiently stringent to protect the public health). The D.C. Circuit rejected petitioners' argument, holding that "[a]lthough we recognize that the Clean Air Act and circuit precedent require EPA qualitatively to describe the standard governing its selection of particular NAAQS, we have expressly rejected the notion that the Agency must 'establish a measure of the risk to safety it considers adequate to protect public health every time it establish a [NAAQS]'" *ATA III*, 283 F. 3d at 369 (quoting *NRDC v. EPA*, 902 F.2d 962, 973 (D.C. Cir. 1990)). The court went on to explain that the requirement is only for EPA to engage in reasoned decision-making, "not that it definitively identify pollutant levels below which risks to public health are negligible." *ATA III*, 283 F. 3d at 370.

Thus, the Administrator is required to exercise her judgment in the face of scientific uncertainty to establish the NAAQS to provide appropriate protection against risks to public health, both known and unknown. As discussed below, in the current review, the Administrator judges that the existing primary O<sub>3</sub> standard is not requisite to protect public health with an adequate margin of safety, a judgment that is consistent with CASAC's conclusion that "there is clear scientific support for the need to revise the standard" (Frey, 2014c, p. ii). Further, in section II.C.4 below, the Administrator has provided a thorough explanation of her rationale for concluding that a standard with a level of 70 ppb is requisite to protect public health with an adequate margin of safety, explaining the various scientific uncertainties which circumscribe the range of potential alternative standards, and how she exercised her "judgment" (per section 109 (b)(1) of the CAA) in selecting a standard from within that range of scientifically reasonable choices. This "reasoned decision making" is what the Act requires, 283 F. 3d at 370, not the quantification advocated by these commenters.

The EPA further disagrees with the comment that a failure to quantify a requisite level of protection impaired or impeded public notice and comment opportunities. In fact, the EPA clearly gave adequate notice of the bases both for determining that the current standard does not afford requisite

protection,<sup>83</sup> and for determining how the standard should be revised. In particular, the EPA explained in detail which evidence it considered critical, and the scientific uncertainties that could cause the Administrator to weight that evidence in various ways (79 FR 75308–75310). There were robust comments submitted by commenters from a range of viewpoints on all of these issues, an indication of the adequacy of notice. The public was also afforded multiple opportunities to comment to the EPA and to CASAC during the development of the ISA, REA, and PA. Thus, the EPA does not agree that lack of quantification of a risk level that is "requisite" has deprived commenters of adequate notice and opportunity to comment in this proceeding.

Various commenters maintained that it was inappropriate to revise the current NAAQS based on their view that natural background concentrations in several states are at or above O<sub>3</sub> concentrations associated with meeting a NAAQS set at a level less than 75 ppb (presumably retaining the same indicator, form, and averaging time), making the NAAQS impossible for those states to attain and maintain, a result they claim is legally impermissible. In support for their argument, the commenters cite monitoring and modelling results from various areas in the intermountain west, state that EPA analyses provide underestimates of background O<sub>3</sub> and conclude that high concentrations of background O<sub>3</sub><sup>84</sup> exist

<sup>83</sup> See 79 FR 75287–91 (noting, among other things, that exposure to ambient O<sub>3</sub> concentrations below the level of the current standard has been associated with diminished lung function capacity, respiratory symptoms, and respiratory health effects resulting in emergency room visits or hospital admissions, and that a single-city epidemiologic study showed associations with asthma emergency department visits in an area that would have met the current standard over the entire study period). See also Frey 2014c, p. 5 (CASAC reiterated its conclusion, after multiple public comment opportunities, that as a matter of science the current standard "is not protective of public health" and provided the bases for that conclusion).

<sup>84</sup> Background O<sub>3</sub> can be generically defined as the portion of O<sub>3</sub> in ambient air that comes from sources outside the jurisdiction of an area and can include natural sources as well as transported O<sub>3</sub> of anthropogenic origin. EPA has identified two specific definitions of background O<sub>3</sub> relevant to this discussion: natural background (NB) and United States background (USB). NB is defined as the O<sub>3</sub> that would exist in the absence of any manmade precursor emissions. USB is defined as that O<sub>3</sub> that would exist in the absence of any manmade emissions inside the U.S. This includes anthropogenic emissions outside the U.S. as well as naturally occurring ozone. In many cases, the comments reference background O<sub>3</sub> only in the generic sense. Unless explicitly noted otherwise, we have assumed all references to background in the comments are intended to refer to USB.

in many parts of the United States that will “prevent attainment” of a revised standard (NMA, p. 5).

The courts have clearly established that “[a]ttainability and technological feasibility are not relevant considerations in the promulgation of [NAAQS].” *API v. EPA*, 665 F. 2d 1176, 1185 (D.C. Cir. 1981). Further, the courts have clarified that the EPA may consider proximity to background concentrations as a factor in the decision whether and how to revise the NAAQS only in the context of considering standard levels within the range of reasonable values supported by the air quality criteria and judgments of the Administrator. 79 FR 75242–43 (citing *ATA III*, 283 F. 3d at 379). In this review, the overall body of scientific evidence and exposure/risk information, as discussed in Section II.B of this notice, is clear and convincing: The existing standard is not adequate to protect public health with an adequate margin of safety and that the standard needs to be revised to reflect a lower level to provide that protection. The EPA analyses indicate that there may be infrequent instances in a limited number of rural areas where background O<sub>3</sub> would be appreciable but not the sole contributor to an exceedance of the revised NAAQS, but do not indicate U.S. background (USB) O<sub>3</sub> concentrations will prevent attainment of a revised O<sub>3</sub> standard with a level of 70 ppb. USB is defined as that O<sub>3</sub> that would exist even in the absence of any manmade emissions within the United States.

The EPA’s estimates of U.S. background ozone concentrations are based on frequently-utilized, state-of-the-science air quality models and are considered reasonable and reliable, not underestimates. In support of their view, the commenters state that monitored (not modelled) ozone concentrations in remote rural locations include instances of 8-hour average concentrations very occasionally higher than 70 ppb. Monitoring data from places like the Grand Canyon and Yellowstone National Parks, are examples cited in comments. It is inappropriate to assume that monitored O<sub>3</sub> concentrations at remote sites can be used as a proxy for background O<sub>3</sub>. Even at the most remote locations, local O<sub>3</sub> concentrations are impacted by anthropogenic emissions from within the U.S. The EPA modeling analyses (U.S. EPA, 2014c, Figure 2–18) estimate that, on a seasonal basis, 10–20% of the O<sub>3</sub> at even the most remote locations in the intermountain western U.S. originates from manmade emissions from the U.S., and thus is not part of

USB. This conclusion is supported by commenter-submitted recent data analyses of rural O<sub>3</sub> observations in Nevada and Utah (NMA, Appendices D and H). These analyses conclude that natural sources, international O<sub>3</sub> transport, O<sub>3</sub> transported from upwind states, and O<sub>3</sub> transported from urban areas within a state all contributed to O<sub>3</sub> concentrations at rural sites.<sup>85</sup> Thus, while O<sub>3</sub> in high-altitude, rural portions of the intermountain western U.S. can, at times, be substantially influenced by background sources such as wildfires, international transport or the stratosphere, measured O<sub>3</sub> in rural locations are also influenced by domestic emissions and so cannot, by themselves, be used to estimate USB concentrations. Accordingly, the fact that 2011–2013 design values in locations like Yellowstone National Park (66 ppb) or Grand Canyon National Park (72 ppb) approach or exceed 70 ppb, does not support the conclusion that a standard with a level of 70 ppb is impossible to attain.

To accurately estimate USB concentrations, it is necessary to use air quality models which can estimate how much of the O<sub>3</sub> at any given location originates from sources other than manmade emissions within the U.S. As part of the rulemaking, the EPA has summarized a variety of modeling-based analyses of background O<sub>3</sub> (U.S. EPA, 2013, Chapter 3) and conducted our own multi-model assessment of USB concentrations across the U.S. (U.S. EPA, 2014c, Chapter 2). The EPA analyses, which are consistent with the previously-summarized studies highlighted by commenters, concluded that seasonal mean daily maximum 8-hour average concentrations of USB O<sub>3</sub> range from 25–50 ppb, with the highest estimates located across the intermountain western U.S.

Importantly, the modeling analyses also indicate that the highest O<sub>3</sub> days (*i.e.*, the days most relevant to the form of the NAAQS) generally have similar daily maximum 8-hour average USB concentrations as the seasonal means of this metric, but have larger contributions from U.S. anthropogenic sources. As summarized in the PA, “the highest modeled O<sub>3</sub> site-days tend to have background O<sub>3</sub> levels similar to mid-range O<sub>3</sub> days . . . [T]he days with

<sup>85</sup> The analysis of observations in Utah notes the influence of domestic emissions—either from Salt Lake City (for two of the areas) or from Los Angeles and California (for the third of the areas)—on O<sub>3</sub> concentrations at each of the locations included (NMA comments, Appendix E). Additionally, the analysis of monitoring data for Nevada also describes the influence of the monitoring sites by domestic emissions from other western states (NMA, Appendix H).

highest O<sub>3</sub> levels have similar distributions (*i.e.* means, inter-quartile ranges) of background levels as days with lower values, down to approximately 40 ppb. As a result, the proportion of total O<sub>3</sub> that has background origins is smaller on high O<sub>3</sub> days (*e.g.* greater than 60 ppb) than on the more common lower O<sub>3</sub> days that tend to drive seasonal means” (U.S. EPA, 2014c, p. 2–21, emphasis added). When averaged over the entire U.S., the models estimate that the mean USB fractional contribution to daily maximum 8-hour average O<sub>3</sub> concentrations above 70 ppb is less than 35 percent. U.S. anthropogenic emission sources are thus the dominant contributor to the majority of modeled O<sub>3</sub> exceedances across the U.S. (U.S. EPA, 2014c, Figures 2–14 and 2–15).

As noted in the PA, and as highlighted by the commenters based on existing modeling, there can be infrequent events where daily maximum 8-hour O<sub>3</sub> concentrations approach or exceed 70 ppb largely due to the influence of USB sources like a wildfire or stratospheric intrusion. As discussed below in Section V, the statute and EPA implementing regulations allow for the exclusion of air quality monitoring data from design value calculations when there are exceedances caused by certain event-related U.S. background influences (*e.g.*, wildfires or stratospheric intrusions). As a result, these “exceptional events” will not factor into attainability concerns.

In sum, the EPA believes that the commenters have failed to establish the predicate for their argument. Uncontrollable background concentrations of O<sub>3</sub> are not expected to preclude attainment of a revised O<sub>3</sub> standard with a level of 70 ppb. The EPA also disagrees with aspects of the specific statements made by the commenters as support for their view that the EPA analyses have underestimated background O<sub>3</sub>.<sup>86</sup> Thus, even assuming the commenters are correct that the EPA may use proximity to background as a justification for not revising a standard that, in the judgment of the Administrator, is inadequate to protect public health, the commenters’ arguments for the justification and need to do so for this review are based on a flawed premise.

#### b. Comments on the Health Effects Evidence

As noted above, comments on the adequacy of the current standard fell into two broad categories reflecting very

<sup>86</sup> Specific aspects of the comments on the EPA analyses are addressed in more detail in the RTC.

different views of the available scientific evidence. Commenters who expressed support for the EPA's proposed decision to revise the current primary O<sub>3</sub> standard generally concluded that the body of scientific evidence assessed in the ISA is much stronger and more compelling than in the last review. These commenters also generally emphasized CASAC's interpretation of the body of available evidence, which formed an important part of the basis for CASAC's reiterated recommendations to revise the O<sub>3</sub> standard to provide increased public health protection. In some cases, these commenters supported their positions by citing studies published since the completion of the ISA.

The EPA generally agrees with these commenters regarding the need to revise the current primary O<sub>3</sub> standard in order to increase public health protection though, in many cases, not with their conclusions about the degree of protection that is appropriate (II.C.4.b and II.C.4.c, below). The scientific evidence noted by these commenters was generally the same as that assessed in the ISA (U.S. EPA, 2013) and the proposal,<sup>87</sup> and their interpretation of the evidence was often, though not always, consistent with the conclusions of the ISA and CASAC. The EPA agrees that the evidence available in this review provides a strong basis for the conclusion that the current O<sub>3</sub> standard is not adequately protective of public health. In reaching this conclusion, the EPA places a large amount of weight on the scientific advice of CASAC, and on CASAC's endorsement of the assessment of the evidence in the ISA (Frey and Samet, 2012).

In contrast, while commenters who opposed the proposed decision to revise the primary O<sub>3</sub> standard generally focused on many of the same studies assessed in the ISA, these commenters highlighted different aspects of these studies and reached substantially different conclusions about their strength and the extent to which progress has been made in reducing uncertainties in the evidence since the last review. These commenters generally concluded that information about the health effects of concern has not changed significantly since 2008 and that the uncertainties in the underlying health science have not been reduced

since the 2008 review. In some cases, these commenters specifically questioned the EPA's approach to assessing the scientific evidence and to reaching conclusions on the strength of that evidence in the ISA. For example, several commenters asserted that the EPA's causal framework, discussed in detail in the ISA, is flawed and that it has not been applied consistently across health endpoints. Commenters also noted departures from other published causality frameworks (Samet and Bodurow, 2008) and from the criteria for judging causality put forward by Sir Austin Bradford Hill (Hill, 1965).

The EPA disagrees with comments questioning the ISA's approach to assessing the evidence, the causal framework established in the ISA, or the consistent application of that framework across health endpoints. While the EPA acknowledges the ISA's approach departs from assessment and causality frameworks that have been developed for other purposes, such departures reflect appropriate adaptations for the NAAQS. As with other ISAs, the O<sub>3</sub> ISA uses a five-level hierarchy that classifies the weight of evidence for causation. In developing this hierarchy, the EPA has drawn on the work of previous evaluations, most prominently the IOM's *Improving the Presumptive Disability Decision-Making Process for Veterans* (Samet and Bodurow, 2008), EPA's Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005), and the U.S. Surgeon General's smoking report (CDC, 2004). The ISA's weight of evidence evaluation is based on the integration of findings from various lines of evidence from across the health and environmental effects disciplines. These separate judgments are integrated into a qualitative statement about the overall weight of the evidence and causality. The ISA's causal framework has been developed over multiple NAAQS reviews, based on extensive interactions with CASAC and based on the public input received as part of the CASAC review process. In the current review, the causality framework, and the application of that framework to causality determinations in the O<sub>3</sub> ISA, have been reviewed and endorsed by CASAC (Frey and Samet, 2012).

Given these views on the assessment of the evidence in the ISA, it is relevant to note that many of the issues and concerns raised by commenters on the EPA's interpretation of the evidence, and on the EPA's conclusions regarding the extent to which uncertainties have been reduced since the 2008 review, are essentially restatements of issues raised during the development of the ISA, HREA, and/or PA. The CASAC O<sub>3</sub> Panel

reviewed the interpretation of the evidence, and the EPA's use of information from specific studies, in drafts of these documents. In CASAC's advice to the Administrator, which incorporates its consideration of many of the issues raised by commenters, CASAC approved of the scientific content, assessments, and accuracy of the ISA, REA, and PA, and indicated that these documents provide an appropriate basis for use in regulatory decision making for the O<sub>3</sub> NAAQS (Frey and Samet, 2012, Frey, 2014a, Frey, 2014c). Therefore, the EPA's responses to many of the comments on the evidence rely heavily on the process established in the ISA for assessing the evidence, which is the product of extensive interactions with CASAC over a number of different reviews, and on CASAC advice received as part of this review of the O<sub>3</sub> NAAQS.

The remainder of this section discusses public comments and the EPA's responses, on controlled human exposure studies (II.B.2.b.i); epidemiologic studies (II.B.2.b.ii); and at-risk populations (II.B.2.b.iii).

#### i. Evidence From Controlled Human Exposure Studies

This section discusses major comments on the evidence from controlled human exposure studies and provides the Agency's responses to those comments. To support their views on the adequacy of the current standard, commenters often highlighted specific aspects of the scientific evidence from controlled human exposure studies. Key themes discussed by these commenters included the following: (1) The adversity of effects demonstrated in controlled human exposure studies, especially studies conducted at exposure concentrations below 80 ppb; (2) representativeness of different aspects of the controlled human exposure studies for making inferences to the general population and at-risk populations; (3) results of additional analyses of the data from controlled human exposure studies; (4) evaluation of a threshold for effects; and (5) importance of demonstration of inflammation at 60 ppb. This section discusses these key comment themes, and provides the EPA's responses. More detailed discussion of individual comments, and the EPA's responses, is provided in the Response to Comments document.

#### Adversity

Some commenters who disagreed with the EPA's proposed decision to revise the current primary O<sub>3</sub> standard disputed the Agency's characterization

<sup>87</sup> As discussed in section I.C above, the EPA has provisionally considered studies that were highlighted by commenters and that were published after the ISA. These studies are generally consistent with the evidence assessed in the ISA, and they do not materially alter our understanding of the scientific evidence or the Agency's conclusions based on that evidence.



of the adversity of the O<sub>3</sub>-induced health effects shown to occur in controlled human exposure studies. Some of these commenters contended that the proposal does not provide a clear definition of adversity or that there is confusion concerning what responses the Administrator considers adverse. The EPA disagrees with these comments, and notes that section II.E.4.d of the proposal describes the Administrator's proposed approach to considering the adversity of effects observed in controlled human exposure studies. Her final approach to considering the adversity of these effects, and her conclusions on adversity, are described in detail below (II.C.4.b, II.C.4.c).

Other commenters disagreed with the EPA's judgments regarding adversity and expressed the view that the effects observed in controlled human exposure studies following 6.6-hour exposures to O<sub>3</sub> concentrations below the level of the current standard (*i.e.*, 75 ppb) are not adverse.<sup>88</sup> This group of commenters cited several reasons to support their views, including that: (1) The lung function decrements and respiratory symptoms observed at 72 ppb in the study by Schelegle et al. (2009) were not correlated with each other, and therefore were not adverse; and (2) group mean FEV<sub>1</sub> decrements observed following exposures below 75 ppb are small (*e.g.*, <10%, as highlighted by some commenters), transient and reversible, do not interfere with daily activities, and do not result in permanent respiratory injury or progressive respiratory dysfunction.

While the EPA agrees that not all effects reported in controlled human exposure studies following exposures below 75 ppb can reasonably be considered to be adverse, the Agency strongly disagrees with comments asserting that none of these effects can be adverse. As an initial matter, the Administrator notes that, when considering the extent to which the current or a revised standard could allow adverse respiratory effects, based on information from controlled human exposure studies, she considers not only the effects themselves, but also quantitative estimates of the extent to which the current or a revised standard could allow such effects. Quantitative

exposure and risk estimates provide perspective on the extent to which various standards could allow populations, including at-risk populations such as children and children with asthma, to experience the types of O<sub>3</sub> exposures that have been shown in controlled human exposure studies to cause respiratory effects. As discussed further below (II.B.3, II.C.4.b, II.C.4.c), to the extent at-risk populations are estimated to experience such exposures repeatedly, the Administrator becomes increasingly concerned about the potential for adverse responses in the exposed population. Repeated exposures provide a plausible mode of action by which O<sub>3</sub> may cause other more serious effects. Thus, even though the Administrator concludes there is important uncertainty in the adversity of some of the effects observed in controlled human exposure studies based on the single exposure periods evaluated in these studies (*e.g.*, FEV<sub>1</sub> decrements observed following exposures to 60 ppb O<sub>3</sub>, as discussed in sections II.C.4.b and II.C.4.c below), she judges that the potential for adverse effects increases as the number of exposures increases. Contrary to the commenters' views noted above, the Administrator considers the broader body of available information (*i.e.*, including quantitative exposure and risk estimates) when considering the extent to which the current or a revised standard could allow adverse respiratory effects (II.B.3, II.C.4.b, II.C.4.c, below).

In further considering commenters' views on the potential adversity of the respiratory effects themselves (*i.e.*, without considering quantitative estimates), the EPA notes that although the results of controlled human exposure studies provide a high degree of confidence regarding the occurrence of health effects following exposures to O<sub>3</sub> concentrations from 60 to 80 ppb, there are no universally accepted criteria by which to judge the adversity of the observed effects. Therefore, as in the proposal, the Administrator relies upon recommendations from the ATS and advice from CASAC to inform her judgments on adversity.

In particular, the Administrator focuses on the ATS recommendation that "reversible loss of lung function in combination with the presence of symptoms should be considered adverse" (ATS, 2000a). The study by Schelegle et al. (2009) reported a statistically significant decrease in group mean FEV<sub>1</sub> and a statistically significant increase in respiratory symptoms in healthy adults following 6.6-hour exposures to average O<sub>3</sub>

concentrations of 72 ppb. In considering these effects, CASAC noted that "the combination of decrements in FEV<sub>1</sub> 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).

As mentioned above, some commenters nonetheless maintained that the effects observed in Schelegle et al. (2009) following exposure to 72 ppb O<sub>3</sub> (average concentration) were not adverse because the magnitudes of the FEV<sub>1</sub> decrements and the increases in respiratory symptoms (as measured by the total subjective symptoms score, TSS) were not correlated across individual study subjects. A commenter submitted an analysis of the individual-level data from the study by Schelegle et al. (2009) to support their position. This analysis indicated that, while the majority of study volunteers (66%) did experience both lung function decrements and increased respiratory symptoms following 6.6-hour exposures to 72 ppb O<sub>3</sub>, some (33%) did not (*e.g.*, Figure 3 in comments from Gradient).<sup>89</sup> In addition, the study subjects who experienced relatively large lung function decrements did not always also experience relatively large increases in respiratory symptoms. These commenters interpreted the lack of a statistically significant correlation between the magnitudes of decrements and symptoms as meaning that the effects reported by Schelegle et al. (2009) at 72 ppb did not meet the ATS criteria for an adverse response.

However, the ATS recommendation that the combination of lung function decrements and symptomatic responses be considered adverse is not restricted to effects of a particular magnitude nor a requirement that individual responses be correlated. Similarly, CASAC made no such qualifications in its advice on the combination of respiratory symptoms and lung function decrements (See *e.g.*, Frey, 2014c, p. 5). Therefore, as in the proposal and consistent with both CASAC advice and ATS recommendations, the EPA continues to conclude that the finding of both statistically significant decrements in lung function and significant increases in respiratory symptoms following 6.6-hour exposures to an average O<sub>3</sub> concentration of 72 ppb provides a strong indication of the

<sup>88</sup> Commenters who supported revising the primary O<sub>3</sub> standard often concluded that there is clear evidence for adverse effects following exposures to O<sub>3</sub> concentrations at least as low as 60 ppb, and that such adverse effects support setting the level of a revised primary O<sub>3</sub> standard at 60 ppb. These comments, and the EPA's responses, are discussed below within the context of the Administrator's decision on a revised level (II.C.4.b).

<sup>89</sup> The figure provided in comments by Gradient only clearly illustrated the responses of 30 out of 31 subjects.



potential for exposed individuals to experience this combination of effects.<sup>90</sup>

In particular, the Administrator notes that lung function provides an objective measure of the respiratory response to O<sub>3</sub> exposure while respiratory symptoms are subjective, and as evaluated by Schelegle et al. (2009) were based on a TSS score. If an O<sub>3</sub> exposure causes increases in both objectively measured lung function decrements and subjective respiratory symptoms, which indicate that people may modify their behavior in response to the exposure, then the effect is properly viewed as adverse. As noted above, the commenter's analysis shows that the majority of study volunteers exposed to 72 ppb O<sub>3</sub> in the study by Schelegle et al. (2009) did, in fact, experience both a decrease in lung function and an increase in respiratory symptoms.

In further considering this comment, the EPA recognizes that, consistent with commenter's analysis, some individuals may experience large decrements in lung function with minimal to no respiratory symptoms (McDonnell et al., 1999), and vice versa. As indicated above and discussed in the proposal (79 FR 75289), the Administrator acknowledges such interindividual variability in responsiveness in her interpretation of estimated exposures of concern. Specifically, she notes that not everyone who experiences an exposure of concern, including for the 70 ppb benchmark, is expected to experience an adverse response. However, she further judges that the likelihood of adverse effects increases as the number of occurrences of O<sub>3</sub> exposures of concern increases. In making this judgment, she notes that the types of respiratory effects that can occur following exposures of concern, particularly if experienced repeatedly, provide a plausible mode of action by which O<sub>3</sub> may cause other more serious effects.<sup>91</sup> Therefore, her decisions on the primary standard emphasize the public health importance of limiting the occurrence of repeated exposures to O<sub>3</sub> concentrations at or above those shown to cause adverse

effects in controlled human exposure studies (II.B.3, II.C.4.b, II.C.4.c). The Administrator views this approach to considering the evidence from controlled human exposure studies as being consistent with commenter's analysis indicating that, while the majority did, not all study volunteers exposed to 72 ppb O<sub>3</sub> experienced the adverse combination of lung function decrements and respiratory symptoms following the single exposure period evaluated by Schelegle et al. (2009).

#### Representativeness

A number of commenters raised issues concerning the representativeness of controlled human exposure studies considered by the Administrator in this review, based on different aspects of these studies. These commenters asserted that since the controlled human exposure studies were not representative of real-world exposures, they should not be relied upon as a basis for finding that the current standard is not adequate to protect public health. Some issues highlighted by commenters include: Small size of the study populations; unrealistic activity levels used in the studies; unrealistic exposure scenarios (*i.e.*, triangular exposure protocol) used in some studies, including Schelegle et al. (2009); and differences in study design that limit comparability across studies.

Some commenters noted that the controlled human exposure studies were not designed to have individuals represent portions of any larger group and that the impacts on a small number of people do not implicate the health of an entire subpopulation, particularly when the FEV<sub>1</sub> decrements are small, temporary, and reversible. These commenters also noted that the Administrator failed to provide an explanation or justification for why the individuals in these studies can be viewed as representatives of a subpopulation. Further, they asserted that EPA's use of results from individuals, rather than the group mean responses, contradicts the intent of CAA section 109 to protect groups of people, not just the most sensitive individuals in any group (79 FR 75237).

Consistent with CASAC advice (Frey, 2014c, p. 5), the EPA concludes that the body of controlled human exposure studies are sufficiently representative to be relied upon as a basis for finding that the current standard is not adequate to protect public health. These studies generally recruit healthy young adult volunteers, and often expose them to O<sub>3</sub> concentrations found in the ambient air under real-world exposure conditions. As described in more detail above in

section II.A.1.b, the evidence from controlled human exposure studies to date makes it clear that there is considerable variability in responses across individuals, even in young healthy adult volunteers, and that group mean responses are not representative of more responsive individuals. It is important to look beyond group mean responses to the responses of these individuals to evaluate the potential impact on more responsive members of the population. Moreover, relying on group mean changes to evaluate lung function responses to O<sub>3</sub> exposures would mask the responses of the most sensitive groups, particularly where, as here, the group mean reflects responses solely among the healthy young adults who were the study participants. Thus, the studies of exposures below 80 ppb O<sub>3</sub> show that 10% of young healthy adults experienced FEV<sub>1</sub> decrements >10% following exposures to 60 ppb O<sub>3</sub>, and 19% experienced such decrements following exposures to 72 ppb (under the controlled test conditions involving moderate exertion for 6.6 hours). These percentages would likely have been higher had people with asthma or other at-risk populations been exposed (U.S. EPA, 2013, pp. 6–17 and 6–18; Frey 2014c, p. 7; Frey, 2014a, p. 14).<sup>92</sup>

Moreover, the EPA may legitimately view the individuals in these studies as representatives of the larger subpopulation of at-risk or sensitive groups. As stated in the Senate Report to the 1970 legislation establishing the NAAQS statutory provisions, "the Committee emphasizes that included among these persons whose health should be protected by the ambient standard are particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment. In establishing an ambient standard necessary to protect the health of these persons, reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group. . . . For purposes of this description, a statistically related sample is the number of persons necessary to test in order to detect a deviation in the health of any person within such sensitive group which is attributable to the condition of the ambient air." S. Rep. No. 11–1196, 91st

<sup>90</sup> Indeed, the finding of statistically significant decreases in lung function and increases in respiratory symptoms in the same study population indicates that, on average, study volunteers did experience both effects.

<sup>91</sup> For example, as discussed in the proposal (79 FR 75252) and the ISA (p. 6–76), inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely. However, 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 (ISA, section 6.2.3).

<sup>92</sup> See also *National Environmental Development Associations Clean Action Project v. EPA*, 686 F. 3d 803, 811 (D.C. Cir. 2012) (EPA drew legitimate inference that serious asthmatics would experience more serious health effects than clinical test subjects who did not have this degree of lung function impairment).

Cong. 2d sess. at 10. As just noted above, 10% of healthy young adults in these studies experienced >10% FEV<sub>1</sub> decrements following exposure to 60 ppb O<sub>3</sub>, and the proportion of individuals experiencing such decrements increases with increasing O<sub>3</sub> exposure concentrations. This substantial percentage certainly can be viewed as “a representative sample of persons” and as a sufficient number to “detect a deviation in the health of any person within such sensitive group,” especially given that it reflects the percentage of *healthy adults* who experienced decrements >10%.

These results are consistent with estimates from the MSS model, which makes reliable quantitative predictions of the lung function response to O<sub>3</sub> exposures, and reasonably predicts the magnitude of individual lung function responses following such exposures. As described in section II.A.2.c above, and documented in the HREA, when the MSS model was used to quantify the risk of O<sub>3</sub>-induced FEV<sub>1</sub> decrements in 15 urban study areas, the current standard was estimated to allow about 8 to 12% of children to experience two or more O<sub>3</sub>-induced FEV<sub>1</sub> decrements ≥10%, and about 2 to 3% to experience two or more decrements ≥15% (Table 2, above). These percentages correspond to hundreds of thousands of children in urban study areas, and tens of thousands of asthmatic children. While the Administrator judges that there is uncertainty with regard to the adversity of these O<sub>3</sub>-induced lung function decrements (see II.C.4.b, II.C.4.c, below), such risk estimates clearly indicate that they are a matter of public health importance on a broad scale, not isolated effects on idiosyncratically responding individuals.

Other commenters considered the ventilation rates used in controlled human exposure studies to be unreasonably high and at the extreme of prolonged daily activity. Some of these commenters noted that these scenarios are unrealistic for sensitive populations, such as asthmatics and people with COPD, whose conditions would likely prevent them from performing the intensity of exercise, and therefore experiencing the ventilation rates, required to produce decrements in lung function observed in experimental settings.

The EPA disagrees with these commenters. The activity levels used in controlled human exposure studies were summarized in Table 6–1 of the ISA (U.S. EPA, 2013). The exercise level in the 6.6-hour exposure studies by Adams (2006), Schelegle et al. (2009), and Kim et al. (2011) of young healthy

adults was moderate and ventilation rates are typically targeted for 20 L/min-m<sup>2</sup> BSA.<sup>93</sup> Following the exposures to 60 ppb at this activity level, 10% of the individuals had greater than a 10% decrement in FEV<sub>1</sub> (U.S. EPA, 2013, p. 6–18). Similar 6.6-hour exposure studies of individuals with asthma are not available to assess either the effects of O<sub>3</sub> on their lung function or their ability to perform the required level of moderate exercise.

However, referring to Tables 6–9 and 6–10 of the HREA (U.S. EPA, 2014a), between 42% and 45% of FEV<sub>1</sub> decrements ≥ 10% were estimated to occur at exercise levels of <13 L/min-m<sup>2</sup> BSA. This corresponds to light exercise, and this level of exercise has been used in a 7.6-hour study of healthy people and people with asthma exposed to 160 ppb O<sub>3</sub> (Horstman et al., 1995). In that study, people with asthma exercised with an average minute ventilation of 14.2 L/min-m<sup>2</sup> BSA. Adjusted for filtered air responses, an average 19% FEV<sub>1</sub> decrement was seen in the people with asthma versus an average 10% FEV<sub>1</sub> decrement in the healthy people. In addition, the EPA noted in the HREA that the data underlying the exposure assessment indicate that “activity data for asthmatics [is] generally similar to [that for] non-asthmatics” (U.S. EPA, 2014a, p. 5–75, Tables 5G–2 and 5G–3). Thus, contrary to the commenters’ assertion, based on both the HREA and the Horstman et al. (1995) study, people with respiratory disease such as asthma can exercise for a prolonged period under conditions where they would experience >10% FEV<sub>1</sub> decrements in response to O<sub>3</sub> exposure.

Additionally, a number of commenters asserted that the exposure scenarios in Schelegle et al. (2009), which are based on a so-called triangular study protocol, where O<sub>3</sub> concentrations ramp up and down as the study is conducted, are not directly generalizable to most healthy or sensitive populations because of large changes in the O<sub>3</sub> concentrations from one hour to the next. Commenters stated that although large fluctuations in O<sub>3</sub> are possible in certain locations due to meteorological conditions (e.g., in valleys on very hot, summer days), they believe that, in general, concentrations of O<sub>3</sub> do not fluctuate by more than 20–30 ppb from one hour to the next. Thus, commenters suggested the Schelegle et

al. (2009) study design could happen in a “worst-case” exposure scenario, but that the exposure protocol was not reflective of conditions in most cities and thus not informative with regard to the adequacy of the current standard.

The EPA disagrees with the comment that these triangular exposure scenarios are not generalizable because of hour-to-hour fluctuations. Adams (2002, 2006) showed that FEV<sub>1</sub> responses following 6.6 hours of exposure to 60 and 80 ppb average O<sub>3</sub> exposures do not differ between triangular (*i.e.* ramping concentration up and down) and square-wave (*i.e.* constant concentration). Schelegle et al. (2009) used the 80 ppb triangular protocol and a slightly modified 60 ppb triangular protocol (concentrations during the third and fourth hours were reversed) from Adams (2006). Therefore, in considering pre- to post-exposure changes in lung function, concerns about the hour-by-hour changes in O<sub>3</sub> concentrations at 60 and 80 ppb in the Schelegle et al. (2009) study are unfounded.

Finally, some commenters also stated that the Kim et al. (2011) study is missing critical information and its study design makes comparison to the other studies difficult. That is, the commenter suggests that data at times other than pre- and post-exposure should have been provided.

The EPA disagrees with this comment. With regard to providing data at other time points besides pre- and post-exposure, there is no standard that suggests an appropriate frequency at which lung function should be measured in prolonged 6.6-hour exposure studies. The Adams (2006) study showed that lung function decrements during O<sub>3</sub> exposures with moderate exercise become most apparent following the third hour of exposure. As such, it makes little sense to measure lung function during the first couple hours of exposure. However, having data at multiple time points toward the end of an exposure can provide evidence that the mean post-exposure FEV<sub>1</sub> response is not a single anomalous data point. The FEV<sub>1</sub> response data for the 3-, 4.6-, 5.6-, and 6.6-hour time points of the Kim et al. (2011) study are available in Figure 6 of the McDonnell et al. (2012) paper where they are plotted with the Adams (2006) data for 60 ppb. Similar to the Adams (2006) study, the responses at 5.6 hours are only marginally smaller than the response at 6.6 hours in the Kim et al. (2011) study. This indicates that the post-exposure FEV<sub>1</sub> responses in both studies are consistent with responses at an earlier time point and thus not likely to be anomalous data.

<sup>93</sup> Exercise consisted of alternating periods walking on a treadmill at a pace of 17–18 minutes per mile inclined to a grade of 4–5% or cycling at a load of about 72 watts. Typical heart rates during the exercise periods were between 115–130 beats per minute. This activity level is considered moderate (Table 6–1, U.S. EPA, 2013, p. 6–18).

### Additional Studies

Several commenters analyzed the data from controlled human exposure studies, or they commented on the EPA's analysis of the data from some of these studies (Brown et al., 2008), to come to a different conclusion than the EPA's interpretation of these studies thereby questioning the proposed decision that the current standard is not adequate to protect public health. One commenter submitted an independent assessment of the scientific evidence and risk, and used this analysis to assert that there are multiple flaws in the underlying studies and their interpretation by the EPA. This commenter stated that the EPA's discussion of the spirometric responses of children and adolescents and older adults to O<sub>3</sub> was misleading. They claimed that the EPA did not mention that "the responses of children and adolescents are equivalent to those of young adults (18–35 years old; McDonnell et al., 1985) and that this response diminishes in middle-aged and older adults (Hazucha 1985)." The EPA notes that the commenter misrepresented our characterization of the effect of age on FEV<sub>1</sub> responses to O<sub>3</sub> and asserted mistakenly that EPA did not mention diminished responses on older adults. In fact, the proposal clearly states that, "Respiratory symptom responses to O<sub>3</sub> exposure appears to increase with age until early adulthood and then gradually decrease with increasing age (U.S. EPA, 1996b); lung function responses to O<sub>3</sub> exposure also decline from early adulthood (U.S. EPA, 1996b)" (79 FR 75267) (see also U.S. EPA, 2014c p. 3–82). With regard to differences between children and adults, it was clearly stated in the ISA (U.S. EPA, 2013, p. 6–21) that healthy children exposed to filtered air and 120 ppb O<sub>3</sub> experienced similar spirometric responses, but lesser symptoms than similarly exposed young healthy adults (McDonnell et al., 1985). In addition, the EPA's approach to modeling the effect of age on responses to O<sub>3</sub> is clearly provided in the HREA (U.S. EPA, 2014a, Table 6–2).

The commenter also stated that the EPA's treatment of filtered air responses in the dose-response curve was incorrect. They claimed that when creating a dose-response curve, it is most appropriate to include a zero-dose point and not to subtract the filtered air response from responses to O<sub>3</sub>. Contrary to this assertion, EPA correctly adjusted FEV<sub>1</sub> responses to O<sub>3</sub> by responses following filtered air, as was also done in the McDonnell et al. (2012) model. As indicated in the ISA (U.S. EPA, 2013, p.

6–4), the majority of controlled human exposure studies investigating the effects O<sub>3</sub> are of a randomized, controlled, crossover design in which subjects were exposed, without knowledge of the exposure condition and in random order, to clean filtered air and, depending on the study, to one or more O<sub>3</sub> concentrations. The filtered air control exposure provides an unbiased estimate of the effects of the experimental procedures on the outcome(s) of interest. Comparison of responses following this filtered air exposure to those following an O<sub>3</sub> exposure allows for estimation of the effects of O<sub>3</sub> itself on an outcome measurement while controlling for independent effects of the experimental procedures, such as ventilation rate. Thus, the commenter's approach does not provide an estimate of the effects of O<sub>3</sub> alone. Furthermore, as illustrated in these comments, following "long" filtered air exposures, there is about a 1% improvement in FEV<sub>1</sub>. By not accounting for this increase in FEV<sub>1</sub>, the commenter underestimated the FEV<sub>1</sub> decrement due to O<sub>3</sub> exposure. The commenter's approach thus is fundamentally flawed.

The commenter also asserted that the McDonnell et al. (2012) model and exposure-response (E–R) models incorrectly used only the most responsive people and that EPA's reliance on data from clinical trials that use only the most responsive people irrationally ignores large portions of relevant data. The EPA rejects this assertion that the McDonnell et al. (2012) model and the E–R analysis ignored large portions of relevant data. The McDonnell et al. (2012) model was fit to the FEV<sub>1</sub> responses of 741 individuals to O<sub>3</sub> and filtered air (*i.e.*, reflecting all available data for O<sub>3</sub>-induced changes in FEV<sub>1</sub>). The filtered air responses were subtracted from responses measured during O<sub>3</sub> exposures. Subsequently, as illustrated by the figures in the McDonnell et al. (2012) paper and described in the text of paper, the model was fit to all available FEV<sub>1</sub> data measured during the course of O<sub>3</sub> exposures, including exposures shorter than 6.6 hours. Thus, the model predicts temporal dynamics of FEV<sub>1</sub> response to any set of O<sub>3</sub> exposure conditions that might reasonably be experienced in the ambient environment, predicting the mean responses and the distribution of responses around the mean. For the HREA (EPA, 2014a), the proportion of individuals, under variable exposure conditions, predicted to have FEV<sub>1</sub>

decrements  $\geq 10$ , 15 and 20% was estimated.

Finally, the commenter referenced the exposure-response model on p. 6–18 of the HREA. However, they neglected to note that this was in a section describing the exposure-response function approach used in prior reviews (U.S. EPA, 2014a, starting on p. 6–17). Thus, the commenter confused the exposure-response model used in the last review with the updated approach used in this review.

The commenter also stated that EPA did not properly consider O<sub>3</sub> dose when interpreting the human clinical data. Ozone total dose includes three factors: duration of exposure, concentration, and ventilation rate. The commenter claimed the EPA emphasized only concentration without properly considering and communicating duration of exposure and ventilation rate. Further, they asserted that because people are not exposed to the same dose, they cannot be judged to have the same exposure and would therefore not be expected to respond consistently. The EPA rejects the claim that we emphasized only concentration without properly incorporating the other two factors. As noted in the ISA, total O<sub>3</sub> dose does not describe the temporal dynamics of FEV<sub>1</sub> responses as a function of concentration, ventilation rate, time and age of the exposed individuals (U.S. EPA, 2013, p. 6–5). Thus, the use of total O<sub>3</sub> dose is antiquated and the EPA therefore conducted a more sophisticated analysis of FEV<sub>1</sub> response to O<sub>3</sub> in the HREA. In this 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 15 urban study areas. A probabilistic model designed to account for the numerous sources of variability that affect people's exposures was used to simulate the movement of individuals through time and space and to estimate their exposure to O<sub>3</sub> while occupying indoor, outdoor, and in-vehicle locations. That information was linked with the McDonnell et al. (2012) model to estimate FEV<sub>1</sub> responses over time as O<sub>3</sub> exposure concentrations and ventilation rates changed. As noted earlier, CASAC agreed that this approach is both scientifically valid and a significant improvement over approaches used in past O<sub>3</sub> reviews (Frey, 2014a, p. 2).

Several commenters criticized the EPA analysis published by Brown et al. (2008). One commenter suggested that the EPA needed to state why the Brown et al. (2008) analysis was relied on rather than Nicolich (2007) or Lefohn et

al. (2010). Further, commenters stated that the analysis of the Adams (2006) data in Brown et al. (2008) was flawed. Among other reasons, one commenter expressed the opinion that it was not appropriate for Brown et al. (2008) to only examine a portion of the Adams (2006) data, citing comments submitted by Gradient.

The EPA disagrees with these commenters.<sup>94</sup> As an initial matter, Nicolich (2007) was a public comment and is not a peer-reviewed publication that would be used to assess the scientific evidence for effects of O<sub>3</sub> on lung function in the ISA (U.S. EPA, 2013). The Nicolich (2007) comments were specifically addressed by the EPA on pp. 24–25 in the Response to Comments Document for the 2007 proposed rule (U.S. EPA, 2008). On page A–3 of his comments, Dr. Nicolich stated “that the residuals are not normally distributed and the observations do not meet the assumptions required for the model” and that “the subject-based errors are not independently, identically and normally distributed and the subjects do not meet the assumptions required for the model.” The EPA reasonably chose not to rely on this analysis: “Therefore, given that the underlying statistical assumptions required for his analyses were not met and that significance levels are questionable, in EPA’s judgment the analyses presented by Dr. Nicolich are ambiguous” (U.S. EPA, 2008). It is likely that the Lefohn et al. (2010) analysis of the Adams (2006) data would similarly not meet the statistical assumptions of the model (*e.g.*, homoscedasticity). In contrast, recognizing the concerns related to the distribution of responses, Brown et al. (2008) conservatively used a nonparametric sign test to obtain a *p*-value of 0.002 for the comparison responses following 60 ppb O<sub>3</sub> versus filter air. Other common statistical tests also showed significant effects on lung function. In addition, the effects of 60 ppb O<sub>3</sub> on FEV<sub>1</sub> responses in Brown et al. (2008) remained statistically significant even following the exclusion of three potential outliers.

EPA disagrees with the comment stating that it was not appropriate for Brown et al. (2008) to only examine a portion of the Adams (2006) data. In

fact, there is no established single manner or protocol decreeing that data throughout the protocol must be analyzed and included. Furthermore, Brown et al. (2008) was a peer-reviewed journal publication. CASAC also expressed favorable comments in their March 30, 2011, letter to Administrator Jackson. With reference to a memorandum (Brown, 2007) that preceded the Brown et al. (2008) publication, on p. 6 of the CASAC Consensus Responses to Charge Questions CASAC stated, “The results of the Adams et al. study also have been carefully reanalyzed by EPA investigators (Brown et al., [2008]), and this reanalysis showed a statistically significant group effect on FEV<sub>1</sub> after 60 ppb ozone exposure.” On p. A–13, a CASAC panelist and biostatistician stated, “Thus, from my understanding of the statistical analyses that have been conducted, I would argue that the analysis by EPA should be preferred to that of Adams for the specific comparison of the FEV<sub>1</sub> effects of 0.06 ppm exposure relative to filtered air exposure.” (Samet 2011, p. a-13)

#### Threshold

Several commenters used the new McDonnell et al. (2012) and Schelegle et al. (2012) models to support their views about the O<sub>3</sub> concentrations associated with a threshold for adverse lung function decrements. For example, one commenter who supported retaining the current standard noted that McDonnell et al. (2012) found that the threshold model fit the observed data better than the original (no-threshold) model, especially at earlier time points and at the lowest exposure concentrations. The commenter expressed the view that the threshold model showed that the population mean FEV<sub>1</sub> decrement did not reach 10% until exposures were at least 80 ppb, indicating that O<sub>3</sub> exposures of 80 ppb or higher may cause lung function decrements and other respiratory effects.<sup>95</sup>

As described above in section II.A.1.b, the McDonnell et al. (2012) and Schelegle et al. (2012) models represent a significant technological advance in the exposure-response modeling approach since the last review, and these models indicate that a dose-threshold model fits the data better than a non-threshold model. However, the

EPA disagrees that using the predicted group mean response from the McDonnell model provides support for retaining the current standard. As discussed above, the group mean responses do not convey information about interindividual variability, or the proportion of the population estimated to experience the larger lung function decrements (*e.g.*, 10 or 15% FEV<sub>1</sub> decrements) that could be adverse. In fact, it masks this variability. These variable effects in individuals have been found to be reproducible. In other words, a person who has a large lung function response after exposure to O<sub>3</sub> will likely have about the same response if exposed again in a similar manner (raising health concerns, as noted above). Group mean responses are not representative of this segment of the population that has much larger than average responses to O<sub>3</sub>.

#### Inflammation

Some commenters asserted that the pulmonary inflammation observed following exposure to 60 ppb in the controlled human exposure study by Kim et al. (2011) was small and unlikely to result in airway damage. It was also suggested that this inflammation is a normal physiological response in all living organisms to stimuli to which people are normally exposed.

The EPA recognized in the proposal (79 FR 75252) and the ISA (U.S. EPA, 2013, p. 6–76) that inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely. Thus, the inflammatory response observed following the single exposure to 60 ppb in the study by Kim et al. (2011) is not necessarily a concern. However, the EPA notes that it is also important to consider the potential for continued acute inflammatory responses to evolve into a chronic inflammatory state and to affect the structure and function of the lung.<sup>96</sup> The Administrator considers this possibility through her consideration of estimated exposures of concern for the 60 ppb benchmark (II.B.3, II.C.4). As discussed in detail below (II.C.4.b), while she judges that there is uncertainty in the adversity of the effects shown to occur following exposures to 60 ppb O<sub>3</sub>, including the inflammation reported by Kim et al.

<sup>94</sup> The DC Circuit has held that EPA reasonably used and interpreted the Brown (2007) study in the last review. *Mississippi*, 744 F. 3d at 1347. In this review, there is now additional corroborative evidence supporting the Brown (2007) analysis, in the form of further controlled human clinical studies finding health effects in young, healthy adults at moderate exercise at O<sub>3</sub> concentrations of 60 ppb over a 6.6 hour exposure period.

<sup>95</sup> Conversely, another group of commenters who supported revising the standard to a level of 60 ppb noted that the results of these models are consistent with the results of controlled human exposure studies finding adverse health effects at 60 ppb. These comments are discussed below (II.C.4.b), within the context of the Administrator’s decision on a revised standard level.

<sup>96</sup> Inflammation induced by exposure of humans to O<sub>3</sub> can have several potential outcomes, ranging from resolving entirely following a single exposure to becoming a chronic inflammatory state (U.S. EPA, 2013, section 6.2.3). Lung injury and the resulting inflammation provide a mechanism by which O<sub>3</sub> may cause other more serious morbidity effects (*e.g.*, asthma exacerbations) (U.S. EPA, 2013, section 6.2.3). See generally section II.A.1.a above.

(2011), she gives some consideration to estimates of two or more exposures of concern for the 60 ppb benchmark (*i.e.*, as a health-protective surrogate for repeated exposures of concern at or above 60 ppb), particularly when considering the extent to which the current and revised standards incorporate a margin of safety.

ii. Evidence From epidemiologic studies

This section discusses key comments on the EPA's assessment of the epidemiologic evidence and provides the Agency's responses to those comments. The focus in this section is on overarching comments related to the EPA's approach to assessing and interpreting the epidemiologic evidence as a whole. Detailed comments on specific studies, or specific methodological or technical issues, are addressed in the Response to Comments document. As discussed above, many of the issues and concerns raised by commenters on the interpretation of the epidemiologic evidence are essentially restatements of issues raised during the development of the ISA, HREA, and/or PA, and in many instances were considered by CASAC in the development of its advice on the current standard. The EPA's responses to these comments rely heavily on the process established in the ISA for assessing the evidence, and on CASAC advice received as part of this review of the O<sub>3</sub> NAAQS.

As with evidence from controlled human exposure studies, commenters expressed sharply divergent views on the evidence from epidemiologic studies, and on the EPA's interpretation of that evidence. One group of commenters, representing medical, public health and environmental organizations, and some states, generally supported the EPA's interpretation of the epidemiologic evidence with regard to the consistency of associations, the coherence with other lines of evidence, and the support provided by epidemiologic studies for the causality determinations in the ISA. These commenters asserted that the epidemiologic studies evaluated in the ISA provide valuable information supporting the need to revise the level of the current primary O<sub>3</sub> standard in order to increase public health protection. In reaching this conclusion, commenters often cited studies (including a number from the past review) which they interpreted as showing health effect associations in locations with O<sub>3</sub> air quality concentrations below the level of the current standard. A second group of commenters, mostly representing

industry associations, businesses, and states opposed to revising the primary O<sub>3</sub> standard, expressed the general view that while many new epidemiologic studies have been published since the last review of the O<sub>3</sub> NAAQS, inconsistencies and uncertainties inherent in these studies as a whole, and in the EPA's assessment of study results, should preclude any reliance on them as justification for a more stringent primary O<sub>3</sub> standard. To support their views, these commenters often focused on specific technical or methodological issues that contribute to uncertainty in epidemiologic studies, including the potential for exposure error, confounding by copollutants and by other factors (*e.g.*, weather, season, disease, day of week, etc.), and heterogeneity in results across locations.

The EPA agrees with certain aspects of each of these views. Specifically, while the EPA agrees that epidemiologic studies are an important part of the broader body of evidence that supports the ISA's causality determinations, and that these studies provide support for the decision to revise the current primary O<sub>3</sub> standard, the Agency also acknowledges that there are important uncertainties and limitations associated with these epidemiologic studies that should be considered when reaching decisions on the current standard. Thus, although these studies show consistent associations between O<sub>3</sub> exposures and serious health effects, including morbidity and mortality, and some of these studies reported such associations with ambient O<sub>3</sub> concentrations below the level of the current standard, there are also uncertainties regarding the ambient O<sub>3</sub> concentrations in critical studies, such that they lend only limited support to establishing a specific level for a revised standard. (See generally, *Mississippi*, 744 F. 3d at 1351 (noting that in prior review, EPA reasonably relied on epidemiologic information in determining to revise the standard but appropriately gave the information limited weight in determining a level of a revised standard); see also *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 current NAAQS); *Mississippi*, 744 F. 3d at 1345 (same)).

Uncertainties in the evidence were considered by the Administrator in the proposal, and contributed to her decision to place less weight on information from epidemiologic studies than on information from controlled human exposure studies when considering the adequacy of the current primary O<sub>3</sub> standard (see 79 FR 75281–

83). Despite receiving less weight in the proposal, the EPA does not agree with commenters who asserted that uncertainties in the epidemiologic evidence provide a basis for concluding that the current primary standard does not need revision. The Administrator specifically considered the extent to which available studies support the occurrence of O<sub>3</sub> health effect associations with air quality likely to be allowed by the current standard, while also considering the implications of important uncertainties, as assessed in the ISA and discussed in the PA. This consideration is consistent with CASAC comments on consideration of these studies in the draft PA (Frey, 2014c, p. 5).

Based on analyses of study area air quality in the PA, the EPA notes that most of the U.S. and Canadian epidemiologic studies evaluated were conducted in locations likely to have violated the current standard over at least part of the study period. Although these studies support the ISA's causality determinations, they provide limited insight into the adequacy of the public health protection provided by the current primary O<sub>3</sub> standard. However, as discussed in the proposal, air quality analyses in the locations of three U.S. single-city studies provide support for the occurrence of O<sub>3</sub>-associated hospital admissions or emergency department visits at ambient O<sub>3</sub> concentrations below the level of the current standard.<sup>97</sup> Specifically, a U.S. single-city study reported associations with respiratory emergency department visits in children and adults in a location that would have met the current O<sub>3</sub> standard over the entire study period (Mar and Koenig, 2009). In addition, for two studies conducted in locations where the current standard was likely not met (*i.e.*, Silverman and Ito, 2010; Strickland et al., 2010), PA analyses indicate that reported concentration-response functions and available air quality data support the occurrence of O<sub>3</sub>-health effect associations on subsets of days with virtually all monitored ambient O<sub>3</sub> concentrations below the level of the current standard (U.S. EPA, 2014c,

<sup>97</sup> As discussed in section II.E.4.d of the proposal, is the Administrator noted the greater uncertainty in using analyses of short-term O<sub>3</sub> air quality in locations of the multicity studies in this review to inform decisions on the primary O<sub>3</sub> standard. This is because the health information in these studies cannot be disaggregated by individual city. Thus, the multicity effect estimates reported in these studies do not provide clear indication of the extent to which health effects are associated with the ambient O<sub>3</sub> concentrations in the study locations that met the current O<sub>3</sub> standard, versus the ambient O<sub>3</sub> concentrations in the study locations that violated the standard.

section 3.1.4.2, pp. 3–66 to 67).<sup>98</sup> Thus, the EPA notes that a small number of O<sub>3</sub> epidemiologic studies provide support for the conclusion that the current primary standard is not requisite, and that it should be revised to increase public health protection.

As part of a larger set of comments criticizing the EPA's interpretation of the evidence from time series epidemiologic studies, some commenters objected to the EPA's reliance on the studies by Strickland et al. (2010), Silverman and Ito (2010), and Mar and Koenig (2009). These commenters highlighted what they considered to be key uncertainties in interpreting these studies, including uncertainties due to the potential for confounding by co-pollutants, aeroallergens, or the presence of upper respiratory infections; and uncertainties in the interpretation of zero-day lag models (*i.e.*, specifically for Mar and Koenig, 2009).

While the EPA agrees that there are uncertainties associated with interpreting the O<sub>3</sub> epidemiologic evidence, as discussed above and elsewhere in this preamble, we disagree with commenters' assertion that these uncertainties should preclude the use of the O<sub>3</sub> epidemiologic evidence in general, or the studies by Silverman and Ito, Strickland, or Mar and Koenig in particular, as part of the basis for the Administrator's decision to revise the current primary standard. As a general point, when considering the potential importance of uncertainties in epidemiologic studies, we rely on the broader body of evidence, not restricted to these three studies, and the ISA conclusions based on this evidence. The evidence, the ISA's interpretation of specific studies, and the use of information from these studies in the HREA and PA, was considered by CASAC in its review of drafts of the ISA, HREA, and PA. Based on the assessment of the evidence in the ISA, and CASAC's endorsement of the ISA conclusions, as well as CASAC's endorsement of the approaches to using and considering information from epidemiologic studies in the HREA and

PA (Frey, 2014c, p. 5), we do not agree with these commenters' conclusions regarding the usefulness of the epidemiologic studies by Strickland et al. (2010), Silverman and Ito (2010), and Mar and Koenig (2009).

More specifically, with regard to confounding by co-pollutants, we note the ISA conclusion that, in studies of O<sub>3</sub>-associated hospital admissions and emergency department visits "O<sub>3</sub> effect estimates remained relatively robust upon the inclusion of PM<sub>10</sub> and gaseous pollutants in two-pollutant models" (U.S. EPA, 2013, pp. 6–152 and 6–153). This conclusion was supported by several studies that evaluated co-pollutant models including, but not limited to, two of the studies specifically highlighted by commenters (*i.e.*, Silverman and Ito, 2010; Strickland et al., 2010) (U.S. EPA, 2013, section 6.2.7.5; Figure 6–20 and Table 6–29).

Other potential uncertainties highlighted by commenters have been evaluated less frequently (*e.g.*, confounding by allergen exposure, respiratory infections). However, we note that Strickland et al. (2010) did consider the potential for pollen (a common airborne allergen) to confound the association between ambient O<sub>3</sub> and emergency department visits. While quantitative results were not presented, the authors reported that "estimates for associations between ambient air pollutant concentrations and pediatric asthma emergency department visits were similar regardless of whether pollen concentrations were included in the model as covariates" (Strickland et al., 2010, p. 309). This suggests a limited impact of aeroallergens on O<sub>3</sub> associations with asthma-related emergency department visits and hospital admissions.

With respect to the comment about epidemiologic studies not controlling for respiratory infections in the model, the EPA disagrees with the commenter's assertion. We recognize that asthma is a multi-etiological disease and that air pollutants, including O<sub>3</sub>, represent only one potential avenue to trigger an asthma exacerbation. Strickland et al. attempted to further clarify the relationship between short-term O<sub>3</sub> exposures and asthma emergency department visits by controlling for the possibility that respiratory infections may lead to an asthma exacerbation. By including the daily count of upper respiratory visits as a covariate in the model, Strickland et al. were able to account for the possibility that respiratory infections contribute to the daily counts of asthma emergency department visits, and to identify the O<sub>3</sub> effect on asthma emergency department

visits. In models that controlled for upper respiratory infection visits, associations between O<sub>3</sub> and emergency department visits remained statistically significant (Strickland et al., Table 4 in published study), demonstrating a relatively limited influence of respiratory infections on the association observed between short-term O<sub>3</sub> exposures and asthma emergency department visits, contrary to the commenter's claim.

In addition, with regard to the criticism of the results reported by Mar and Koenig, the EPA disagrees with commenters who questioned the appropriateness of a zero-day lag. These commenters specifically noted uncertainty in the relative timing of the O<sub>3</sub> exposure and the emergency department visit when they occurred on the same day. However, based on the broader body of evidence the ISA concludes that the strongest support is for a relatively immediate respiratory response following O<sub>3</sub> exposures. Specifically, the ISA states that "[t]he collective evidence indicates a rather immediate response within the first few days of O<sub>3</sub> exposure (*i.e.*, for lags days averaged at 0–1, 0–2, and 0–3 days) for hospital admissions and [emergency department] visits for all respiratory outcomes, asthma, and chronic obstructive pulmonary disease in all-year and seasonal analyses" (U.S. EPA, 2013, p. 2–32). Thus, the use of a zero-day lag is consistent with the broader body of evidence supporting the occurrence of O<sub>3</sub>-associated health effects. In addition, while Mar and Koenig reported the strongest associations for zero-day lags, they also reported positive associations for lags ranging from zero to five days (Mar and Koenig, 2009, Table 5 in the published study). In considering this study, the ISA stated that Mar and Koenig (2009) "found consistent positive associations across individual lag days" and that "[f]or children, consistent positive associations were observed across all lags . . . with the strongest associations observed at lag 0 (33.1% [95% CI: 3.0, 68.5]) and lag 3 (36.8% [95% CI: 6.1, 77.2])" (U.S. EPA, 2013, p. 6–150). Given support for a relatively immediate response to O<sub>3</sub> and given the generally consistent results in analyses using various lags, we disagree with commenters who asserted that the use of a zero-day lag represents an important uncertainty in the interpretation of the study by Mar and Koenig (2009).

Given all of the above, we do not agree with commenters who asserted that uncertainties in the epidemiologic evidence in general, or in specific key studies, should preclude the

<sup>98</sup> Air quality analyses in locations of the studies by Silverman and Ito (2010) and Strickland et al. (2010) were used in the PA to inform staff conclusions on the adequacy of the current primary O<sub>3</sub> standard. However, the appropriate interpretation of these analyses became less clear for standard levels below 75 ppb, as the number of days increased with monitored concentrations exceeding the level being evaluated (U.S. EPA, 2014c, Appendix 3B, Tables 3B–6 and 3B–7). Therefore, these analyses were not used in the PA to inform conclusions on potential alternative standard levels lower than 75 ppb (U.S. EPA, 2014c, Chapters 3 and 4).

Administrator from relying on those studies to inform her decisions on the primary O<sub>3</sub> standard.

Some commenters also objected to the characterization in the ISA and the proposal that the results of epidemiologic studies are consistent. These commenters contended that the purported consistency of results across epidemiologic studies is the result of inappropriate selectivity on the part of the EPA in focusing on specific studies and specific results within those studies. In particular, commenters contend that EPA favors studies that show positive associations and selectively ignores certain studies that report null results. They also cite a study published after the completion of the ISA (Goodman et al., 2013) suggesting that, in papers where the results of more than one statistical model are reported, the EPA tends to report the results with the strongest associations.

The EPA disagrees that it has inappropriately focused on specific positive studies or specific positive results within individual studies. The ISA appropriately builds upon the assessment of the scientific evidence presented in previous AQCDs and ISAs.<sup>99</sup> When evaluating new literature, “[s]election of studies for inclusion in the ISA is based on the general scientific quality of the study, and consideration of the extent to which the study is informative and policy-relevant” (U.S. EPA, 2013, p. liii). In addition, “the intent of the ISA is to provide a concise review, synthesis, and evaluation of the most policy-relevant science to serve as a scientific foundation for the review of the NAAQS, not extensive summaries of all health, ecological and welfare effects studies for a pollutant” (U.S. EPA, 2013, p. lv). Therefore, not all studies published since the previous review would be appropriate for inclusion in the ISA.<sup>100</sup> With regard to the specific

studies that are included in the ISA, and the analyses focused upon within given studies, the EPA notes that the ISA undergoes extensive peer review in a public setting by the CASAC. This process provides ample opportunity for CASAC and the public to comment on studies not included in the ISA, and on the specific analyses focused upon within individual studies. In endorsing the final O<sub>3</sub> ISA as adequate for rule-making purposes, CASAC agreed with the selection and presentation of analyses on which to base the ISA’s key conclusions.

### iii. Evidence Pertaining to At-Risk Populations and Lifestyles

A number of groups submitted comments on the EPA’s identification of at-risk populations and lifestyles. Some industry commenters who opposed revising the current standard disagreed with the EPA’s identification of people with asthma or other respiratory diseases as an at-risk population for O<sub>3</sub>-attributable effects, citing controlled human exposure studies that did not report larger O<sub>3</sub>-induced FEV<sub>1</sub> decrements in people with asthma than in people without asthma. In contrast, comments from medical, environmental, and public health groups generally agreed with the at-risk populations identified by EPA, and also identified other populations that they stated should be considered at risk, including people of lower socio-economic status, people with diabetes or who are obese, pregnant women (due to reproductive and developmental effects, and African American, Asian, Hispanic/Latino or tribal communities. As support for the additional populations, these commenters cited various studies, including some that were not included in the ISA (which we have provisionally considered, as described in section I.C above).

With regard to the former group of comments stating that the evidence does not support the identification of asthmatics as an at-risk population, we disagree. As summarized in the proposal, the EPA’s identification of populations at risk of O<sub>3</sub> effects is based on a systematic approach that assesses the current scientific evidence across the relevant scientific disciplines (*i.e.*, exposure sciences, dosimetry, controlled human exposure, toxicology, and epidemiology), with a focus on studies that conducted stratified analyses allowing for an evaluation of different populations exposed to similar

O<sub>3</sub> concentrations within the same study design (U.S. EPA, 2013, pp. 8–1 to 8–3). Based on this established process and framework, the ISA identifies individuals with asthma among the populations and lifestages for which there is “adequate” evidence to support the conclusion of increased risk of O<sub>3</sub>-related health effects. Other populations for which the evidence is adequate are individuals with certain genotypes, younger and older age groups, individuals with reduced intake of certain nutrients, and outdoor workers. These conclusions are based on consistency in findings across studies and evidence of coherence in results from different scientific disciplines.

For example, with regard to people with asthma, the ISA notes a number of epidemiologic and controlled human exposure studies reporting larger and/or more serious effects in people with asthma than in people without asthma or other respiratory diseases. These include epidemiologic studies of lung function, respiratory symptoms, and medication use, as well as controlled human exposure studies showing larger inflammatory responses and markers indicating altered immune functioning in people with asthma, and also includes evidence from animal models of asthma that informs the EPA’s interpretation of the other studies. We disagree with the industry commenters’ focus solely on the results of certain studies without an integrated consideration of the broader body of evidence, and wider range of respiratory endpoints. It is such an integrated approach that supports EPA’s conclusion that “there is adequate evidence for asthmatics to be an at-risk population” (U.S. EPA, 2013, section 8.2.2).

We also disagree with commenters’ misleading reference to various studies cited to support the claim that asthmatics are not at increased risk of O<sub>3</sub>-related health effects. One of the controlled human studies cited in those comments (Mudway et al. 2001) involved asthmatic adults who were older than the healthy controls, and it is well-recognized that responses to O<sub>3</sub> decrease with age (U.S. EPA, 2014c, p. 3–80). Another study (Alexis et al. 2000) used subjects with mild asthma who are unlikely to be as responsive as people with more severe disease (Horstman et al., 1995) (EPA 2014c, p. 3–80). Controlled human exposure studies and epidemiologic studies of adults and children amply confirm that “there is adequate evidence for asthmatics to be an at-risk population” (U.S. EPA, 2014c, p. 3–81).

<sup>99</sup>Cf. *Coalition for Responsible Regulation v. EPA*, 684 F. 3d 102, 119 (D.C. Cir. 2012) (aff’d in part and rev’d in part on other grounds sub. nom. *UARG v. EPA*, S Ct. (2014)) (“EPA simply did here what it and other decision-makers often must do to make a science-based judgment: it sought out and reviewed existing scientific evidence to determine whether a particular finding was warranted. It makes no difference that much of the scientific evidence in large part consisted of ‘syntheses’ of individual studies and research. Even individual studies and research papers often synthesize past work in an area and then build upon it. That is how science works”).

<sup>100</sup> See also section II.C.4.b below responding to comments from environmental interests that EPA inappropriately omitted many studies which (in their view) support establishing a revised standard at a level of 60 ppb or lower. Although, as explained there, the EPA disagrees with these comments, the comments illustrate that the EPA was even-handed in its consideration of the

epidemiologic evidence, and most certainly did not select merely studies favorable to the point of view of revising the current standard.



We also do not agree with the latter group of commenters that there is sufficient evidence to support the identification of additional populations as at risk of O<sub>3</sub>-attributable health effects. Specifically with regard to pregnant women, the ISA concluded that the “evidence is suggestive of a causal relationship between exposures to O<sub>3</sub> and reproductive and developmental effects” including birth outcomes, noting that “the collective evidence for many of the birth outcomes examined is generally inconsistent” (U.S. EPA, 2013, pp. 7–74 and 7–75). At the time of the completion of the ISA, no studies had been identified that examined the relationship between exposure to O<sub>3</sub> and the health of pregnant women (*e.g.*, studies on pre-eclampsia, gestational hypertension). Due to the generally inconsistent epidemiologic evidence for effects on birth outcomes, the lack of studies on the health of pregnant women, and the lack of studies from other disciplines to provide biological plausibility for the effects examined in epidemiologic studies, pregnant women were not considered an at-risk population. Based on the EPA’s provisional consideration of studies published since the completion of the ISA (I.C, above), recent studies that examine exposure to O<sub>3</sub> and pre-eclampsia and other health effects experienced by pregnant women are not sufficient to materially change the ISA’s conclusions on at-risk populations (I.C, above). In addition, as summarized in the proposal, the ISA concluded that the evidence for other populations was either suggestive of increased risk, with further investigation needed (*e.g.*, other genetic variants, obesity, sex, and socioeconomic status), or was inadequate to determine if they were of increased risk of O<sub>3</sub>-related health effects (influenza/infection, COPD, CVD, diabetes, hyperthyroidism, smoking, race/ethnicity, and air conditioning use) (U.S. EPA, 2013, section 2.5.4.1). The CASAC has concurred with the ISA conclusions (Frey, 2014c).

### c. Comments on Exposure and Risk Assessments

This section discusses major comments on the EPA’s quantitative assessments of O<sub>3</sub> exposures and health risks, presented in the HREA and considered in the PA, and the EPA’s responses to those comments. The focus in this section is on overarching comments related to the EPA’s approach to assessing exposures and risks, and to interpreting the exposure/risk results within the context of the adequacy of the current primary O<sub>3</sub> standard. More

detailed discussion of comments and Agency responses is provided in the Response to Comments document. Section II.B.2.c.i discusses comments on estimates of O<sub>3</sub> exposures of concern, section II.B.2.c.ii discusses comments on estimates of the risk of O<sub>3</sub>-induced lung function decrements, and section II.B.2.b.iii discusses comments on estimates of the risk of O<sub>3</sub>-associated mortality and morbidity.

#### i. O<sub>3</sub> Exposures of Concern

The EPA received a number of comments expressing divergent views on the estimation of, and interpretation of, O<sub>3</sub> exposures of concern. In general, comments from industry, business, and some state groups opposed to revising the current primary O<sub>3</sub> standard asserted that the approaches and assumptions that went into the HREA assessment result in overestimates of O<sub>3</sub> exposures. These commenters highlighted several aspects of the assessment, asserting that the HREA overestimates the proportion of the population expected to achieve ventilation rates high enough to experience an exposure of concern; that the use of out-of-date information on activity patterns results in overestimates of the amount of time people spend being active outdoors; and that exposure estimates do not account for the fact that people spend more time indoors on days with bad air quality (*i.e.*, they engage in averting behavior). In contrast, comments from medical, public health, and environmental groups that supported revision of the current standard asserted that the HREA assessment of exposures of concern, and the EPA’s interpretation of exposure estimates, understates the potential for O<sub>3</sub> exposures that could cause adverse health effects. These commenters claimed that the EPA’s focus on 8-hour exposures understates the O<sub>3</sub> impacts on public health since effects in controlled human exposure studies were shown following 6.6-hour exposures; that the HREA exposure estimates do not capture the most highly exposed populations, such as highly active children and outdoor workers; and that the EPA’s interpretation of estimated exposures of concern impermissibly relies on the assumption that people stay indoors to avoid dangerous air pollution (*i.e.*, that they engage in averting behavior).

In considering these comments, the EPA first notes that as discussed in the HREA, PA, and the proposal, there are aspects of the exposure assessment that, considered by themselves, can result in either overestimates or underestimates of the occurrence of O<sub>3</sub> exposures of

concern. Commenters tended to highlight the aspects of the assessment that supported their positions, including aspects that were discussed in the HREA and/or the PA and that were considered by CASAC. In contrast, commenters tended to ignore the aspects of the assessment that did not support their positions. The EPA has carefully described and assessed the significance of the various uncertainties in the exposure analysis (U.S. EPA, 2014a, Table 5–10), noting that, in most instances, the uncertainties could result in either overestimates or underestimates of exposures and that the magnitudes of the impacts on exposure results were either “low,” “low to moderate,” or “moderate” (U.S. EPA, 2014a, Table 5–10).

Consistent with the characterization of uncertainties in the HREA, PA, and the proposal, the EPA agrees with some, though not all, aspects of these commenters’ views. For example, the EPA agrees with the comment by groups opposed to revision that the equivalent ventilation rate (EVR) used to characterize individuals as at moderate or greater exertion in the HREA likely leads to overestimates of the number of individuals experiencing exposures of concern (U.S. EPA, 2014a, Table 5–10, p. 5–79). In addition, we note that other physiological processes that are incorporated into exposure estimates are also identified in the HREA as likely leading to overestimates of O<sub>3</sub> exposures, based on comparisons with the available scientific literature (U.S. EPA, 2014a, Table 5–10, p. 5–79). These aspects of the exposure assessment are estimated to have either a “moderate” (*i.e.*, EVR) or a “low to moderate” (*i.e.*, physiological processes) impact on exposure estimates (U.S. EPA, 2014a, Table 5–10, p. 5–79). Focusing on these aspects of the assessment, by themselves, could lead to the conclusion that the HREA overstates the occurrence of O<sub>3</sub> exposures of concern.

However, the EPA notes that there are also aspects of the HREA exposure assessment that, taken by themselves, could lead to the conclusion that the HREA understates the occurrence of O<sub>3</sub> exposures of concern. For example, as noted above, some medical, public health, and environmental groups asserted that the exposure assessment could underestimate O<sub>3</sub> exposures for highly active populations, including outdoor workers and children who spend a large portion of time outdoors during summer. In support of these assertions, commenters highlighted sensitivity analyses conducted in the HREA. However, as noted in the HREA (U.S. EPA, 2014a, Table 5–10), this



aspect of the assessment is likely to have a “low to moderate” impact on exposure estimates (*i.e.*, a smaller impact than uncertainty associated with the EVR, and similar in magnitude to uncertainties related to physiological processes, as noted above). Therefore, when considered in the context of all of the uncertainties in exposure estimates, it is unlikely that the HREA’s approach to using data on activity patterns leads to overall underestimates of O<sub>3</sub> exposures. The implications of this uncertainty are discussed in more detail below (II.C.4.b), within the context of the Administrator’s decision on a revised standard level.

In addition, medical, public health, and environmental groups also pointed out that the controlled human exposures studies that provided the basis for health effect benchmarks were conducted in healthy adults, rather than at-risk populations, and these studies evaluated 6.6 hour exposures, rather than the 8-hour exposures evaluated in the HREA exposure analyses. They concluded that adverse effects would occur at lower exposure concentrations in at-risk populations, such as people with asthma, and if people were exposed for 8 hours, rather than 6.6 hours. In its review of the PA, CASAC clearly recognized these uncertainties, which provided part of the basis for CASAC’s advice to consider exposures of concern for the 60 ppb benchmark. For example, when considering the results of the study by Schelegle et al. (2009) for 6.6-hour exposures to an average O<sub>3</sub> concentration of 72 ppb, CASAC judged that if subjects had been exposed for eight hours, the adverse combination of lung function decrements and respiratory symptoms “could have occurred” at lower O<sub>3</sub> exposure concentrations (Frey, 2014c, p. 5). With regard to at-risk populations, CASAC concluded that “based on results for clinical studies of healthy adults, and scientific considerations of differences in responsiveness of asthmatic children compared to healthy adults, there is scientific support that 60 ppb is an appropriate exposure of concern for asthmatic children” (Frey, 2014c, p. 8). As discussed below (II.B.3, II.C.4.b, II.C.4.c), based in large part on CASAC advice, the Administrator does consider exposure results for the 60 ppb benchmark.

Thus, rather than viewing the potential implications of various aspects of the HREA exposure assessment in isolation, as was done by many commenters, the EPA considers them together, along with other issues and uncertainties related to the interpretation of exposure estimates. As

discussed above, CASAC recognized the key uncertainties in exposure estimates, as well as in the interpretation of those estimates in the HREA and PA (Frey, 2014a, c). In its review of the 2nd draft REA, CASAC concluded that “[t]he discussion of uncertainty and variability is comprehensive, appropriately listing the major sources of uncertainty and their potential impacts on the APEX exposure estimates” (Frey, 2014a, p. 6). Even considering these and other uncertainties, CASAC emphasized estimates of O<sub>3</sub> exposures of concern as part of the basis for their recommendations on the primary O<sub>3</sub> NAAQS. In weighing these uncertainties, which can bias exposure results in different directions but tend to have impacts that are similar in magnitude (U.S. EPA, 2014a, Table 5–10), and in light of CASAC’s advice based on its review of the HREA and the PA, the EPA continues to conclude that the approach to considering estimated exposures of concern in the HREA, PA, and the proposal reflects an appropriate balance, and provides an appropriate basis for considering the public health protectiveness of the primary O<sub>3</sub> standard.

The EPA disagrees with other aspects of commenters’ views on HREA estimates of exposures of concern. For example, commenters on both sides of the issue objected to the EPA’s handling of averting behavior in exposure estimates. Some commenters who supported retaining the current standard claimed that the HREA overstates exposures of concern because available time-location-activity data do not account for averting behavior. These commenters noted sensitivity analyses in the HREA that estimated fewer exposures of concern when averting behavior was considered. In contrast, commenters supporting revision of the standard criticized the EPA’s estimates of exposures of concern, claiming that the EPA “emphasizes the role of averting behavior, noting that it may result in an overestimation of exposures of concern, and cites this behavior (essentially staying indoors or not exercising) in order to reach what it deems an acceptable level of risk” (*e.g.*, ALA et al., p. 120).

The EPA disagrees with both of these comments. In brief, the NAAQS must “be established at a level necessary to protect the health of persons,” not the health of persons refraining from normal activity or resorting to medical interventions to ward off adverse effects of poor air quality (S. Rep. No. 11–1196, 91st Cong. 2d Sess. at 10). On the other hand, ignoring normal activity patterns for a pollutant like O<sub>3</sub>, where adverse

responses are critically dependent on ventilation rates, will result in a standard which provides more protection than is requisite. This issue is discussed in more detail below (II.C.4.b), within the context of the Administrator’s decision on a revised standard level.

These commenters also misconstrue the EPA’s limited sensitivity analyses on impacts of averting behavior in the HREA. The purpose of the HREA sensitivity analyses was to provide perspective on the potential role of averting behavior in modifying O<sub>3</sub> exposures. These sensitivity analyses were limited to a single urban study area, a 2-day period, and a single air quality adjustment scenario (U.S. EPA, 2014a, section 5.4.3.3). In addition, the approach used in the HREA to simulate averting behavior was itself uncertain, given the lack of actual activity pattern data that explicitly incorporated this type of behavioral response. In light of these important limitations, sensitivity analyses focused on averting behavior were discussed in the proposal within the context of the discussion of uncertainties in the HREA assessment of exposures of concern (II.C.2.b in the proposal) and, contrary to the claims of some commenters, they were not used to support the proposed decision.

Some industry groups also claimed that the time-location-activity diaries used by APEX to estimate exposures are out-of-date, and do not represent activity patterns in the current population. These commenters asserted that the use of out-of-date diary information leads to overestimates in exposures of concern. This issue was explicitly addressed in the HREA and the EPA disagrees with commenters’ conclusions. In particular, diary data was updated in this review to include data from studies published as late as 2010, directly in response to CASAC concerns. In their review of this data, CASAC stated that “[t]he addition of more recent time activity pattern data addresses a concern raised previously by the CASAC concerning how activity pattern information should be brought up to date” (Frey, 2014a, p. 8). As indicated in the HREA (U.S. EPA, 2014a, Appendix 5G, Figures 5G–7 and Figure 5G–8), the majority of diary days used in exposure simulations of children originate from the most recently conducted activity pattern studies (U.S. EPA, 2014a, Table 5–3). In addition, evaluations included in the HREA indicated that there were not major systematic differences in time-location-activity patterns based on information from older diaries versus those collected more recently (U.S. EPA,

2014a, Appendix 5G, Figures 5G–1 and 5G–2). Given all of the above, the EPA does not agree with commenters who claimed that the time-location-activity diaries used by APEX are out-of-date, and result in overestimates of exposures of concern.

#### ii. Risk of O<sub>3</sub>-Induced FEV<sub>1</sub> Decrements

The EPA also received a large number of comments on the FEV<sub>1</sub> risk assessment presented in chapter 6 of the HREA (U.S. EPA, 2014a) and summarized in the proposal (II.C.3.a in the proposal). Commenters representing medical, public health, and environmental groups generally expressed the view that these risk estimates support the need to revise the current primary O<sub>3</sub> standard in order to increase public health protection, though these groups also questioned some of the assumptions inherent in the EPA's interpretation of those risk estimates. For example, ALA et al. (p. 127) stated that “[t]he HREA uses a risk function derived from a controlled human exposure study of healthy young adults to estimate lung function decrements in children, including children with asthma. This assumption could result in an underestimate of risk.” On this same issue, commenters representing industry groups opposed to revising the standard also asserted that assumptions about children's responses to O<sub>3</sub> exposures are highly uncertain. In contrast to medical and public health groups, these commenters concluded that this uncertainty, along with others discussed below, call into question the use of FEV<sub>1</sub> risk estimates to support a decision to revise the current primary O<sub>3</sub> standard.

The EPA agrees that an important source of uncertainty is the approach to estimating the risk of FEV<sub>1</sub> decrements in children and in children with asthma based on data from healthy adults. However, this issue is discussed at length in the HREA and the PA, and was considered carefully by CASAC in its review of draft versions of these documents. The conclusions of the HREA and PA, and the advice of CASAC, were reflected in the Administrator's interpretation of FEV<sub>1</sub> risk estimates in the proposal, as described below. Commenters have not provided additional information that changes the EPA's views on this issue.

As discussed in the proposal (II.C.3.a.ii in the proposal), 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<sub>3</sub> exposures as healthy 18-year olds (*i.e.*, the youngest age for

which sufficient controlled human exposure data is available) (U.S. EPA, 2014a, section 6.5.3). As noted by CASAC (Frey, 2014a, p. 8), this assumption is justified in part by the findings of McDonnell et al. (1985), who reported that children (8–11 years old) experienced FEV<sub>1</sub> responses similar to those observed in adults (18–35 years old). The HREA concludes that this approach could result in either over- or underestimates of O<sub>3</sub>-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). With regard to people with asthma, although the evidence has been mixed (U.S. EPA, 2013, section 6.2.1.1), several studies have reported statistically larger, or a tendency for larger, O<sub>3</sub>-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 O<sub>3</sub>-induced pulmonary function decrements” (Frey, 2014c, p. 4). To the extent asthmatics experience larger O<sub>3</sub>-induced lung function decrements than the healthy adults used to develop exposure-response relationships, the HREA could underestimate the impacts of O<sub>3</sub> exposures on lung function in asthmatics, including asthmatic children (U.S. EPA, 2014a, section 6.5.4). As noted above, these uncertainties have been considered carefully by the EPA and by CASAC during the development of the HREA and PA. In addition, the Administrator has appropriately considered these and other uncertainties in her interpretation of risk estimates, as discussed further below (II.B.3, II.C.4.b, II.C.4.c).

Some commenters additionally asserted that the HREA does not appropriately characterize the uncertainty in risk estimates for O<sub>3</sub>-induced lung function decrements. Commenters pointed out that there is statistical uncertainty in model coefficients that is not accounted for in risk estimates. One commenter presented an analysis of this uncertainty, and concluded that there is considerable overlap between risk estimates for standard levels of 75, 70, and 65 ppb, undercutting the confidence in estimated risk reductions for standard levels below 75 ppb.

The Agency recognizes that there are important sources of uncertainty in the FEV<sub>1</sub> risk assessment. In some cases, these sources of uncertainty can

contribute to substantial variability in risk estimates, complicating the interpretation of those estimates. For example, as discussed in the proposal, the variability in FEV<sub>1</sub> risk estimates across urban study areas is often greater than the differences in risk estimates between various standard levels (Table 2, above and 79 FR 75306 n. 164). Given this, and the resulting considerable overlap between the ranges of FEV<sub>1</sub> risk estimates for different standard levels, in the proposal the Administrator viewed these risk estimates as providing a more limited basis than exposures of concern for distinguishing between the degree of public health protection provided by alternative standard levels. Thus, although the EPA does not agree with the overall conclusions of industry commenters, their analysis of statistical uncertainty in risk estimates, and the resulting overlap between risk estimates for standard levels of 75, 70, and 65 ppb, tends to reinforce the Administrator's approach, which places greater weight on estimates of O<sub>3</sub> exposures of concern than on risk estimates for O<sub>3</sub>-induced FEV<sub>1</sub> decrements.

#### iii. Risk of O<sub>3</sub>-Associated Mortality and Morbidity

In the proposal, the Administrator placed the greatest emphasis on the results of controlled human exposure studies and on quantitative analyses based on information from these studies, and less weight on mortality and morbidity risk assessments based on information from epidemiology studies. The EPA received a number of comments on its consideration of epidemiology-based risks, with some commenters expressing support for the Agency's approach and others expressing opposition.

In general, commenters representing industry organizations or states opposed to revising the current primary O<sub>3</sub> standard agreed with the Administrator's approach in the proposal to viewing epidemiology-based risk estimates, though these commenters reached a different conclusion than the EPA regarding the adequacy of the current standard. In supporting their views, these commenters highlighted a number of uncertainties in the underlying epidemiologic studies, and concluded that risk estimates based on information from such studies do not provide an appropriate basis for revising the current standard. For example, commenters noted considerable spatial heterogeneity in health effect associations; the potential for co-occurring pollutants (*e.g.*, PM<sub>2.5</sub>) to confound O<sub>3</sub> health effect associations;

and the lack of statistically significant O<sub>3</sub> health effect associations in many of the individual cities evaluated as part of multicity analyses. In contrast, some commenters representing medical, public health, or environmental organizations placed greater emphasis than the EPA on epidemiology-based risk estimates. These commenters asserted that risk estimates provide strong support for a lower standard level, and pointed to CASAC advice to support their position.

As in the proposal, the EPA continues to place the greatest weight on the results of controlled human exposure studies and on quantitative analyses based on information from these studies (particularly exposures of concern, as discussed below in II.B.3 and II.C.4), and less weight on risk analyses based on information from epidemiologic studies. In doing so, the Agency continues to note that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following specific O<sub>3</sub> exposures. In addition, the effects reported in these studies are due solely to O<sub>3</sub> 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). The Agency 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 than the results of epidemiology-based risk analyses. As discussed in the HREA (U.S. EPA, 2014a, section 9.6), several key uncertainties complicate the interpretation of these epidemiology-based risk estimates, including the heterogeneity in O<sub>3</sub> effect estimates between locations, the potential for exposure measurement errors in these epidemiologic studies, and uncertainty in the interpretation of the shape of concentration-response functions at lower O<sub>3</sub> concentrations. Commenters who opposed the EPA’s approach in the proposal to viewing the results of quantitative analyses tended to highlight aspects of the evidence and CASAC advice that were considered by the EPA at the time of proposal and nothing in these commenters’ views has changed those considerations.

Therefore, the EPA continues to place the most emphasis on using the information from controlled human exposure studies to inform consideration of the adequacy of the primary O<sub>3</sub> standard.

However, while the EPA agrees that there are important uncertainties in the O<sub>3</sub> epidemiology-based risk estimates, the Agency disagrees with industry commenters that these uncertainties support a conclusion to retain the current standard. As discussed below, the decision to revise the current primary O<sub>3</sub> standard is based on the EPA’s consideration of the broad body of scientific evidence, quantitative analyses of O<sub>3</sub> exposures and risks, CASAC advice, and public comments. While recognizing uncertainties in the epidemiology-based risk estimates here, and giving these uncertainties appropriate consideration, the Agency continues to conclude that these risk estimates contribute to the broader body of evidence and information supporting the need to revise the primary O<sub>3</sub> standard.

Some commenters opposed to revising the current O<sub>3</sub> standard highlighted the fact that, in a few urban study locations, larger risks are estimated for standard levels below 75 ppb than for the current standard with its level of 75 ppb. For example, TCEQ (p. 3) states that “differential effects on ozone in urban areas also lead to the EPA’s modeled increases in mortality in Houston and Los Angeles with decreasing ozone standards.” These commenters cited such increases in estimated risk as part of the basis for their conclusion that the current standard should be retained.

For communities across the U.S. (including in the Houston and Los Angeles areas), exposure and risk analyses indicate that reducing emissions of O<sub>3</sub> precursors (NO<sub>x</sub>, VOCs) to meet a revised standard with a level of 70 ppb will substantially reduce the occurrence of adverse respiratory effects and mortality risk attributable to high O<sub>3</sub> concentrations (U.S. EPA, 2014a, Appendix 9A; U.S. EPA, 2014c, sections 4.4.2.1 to 4.4.2.3). However, because of the complex chemistry governing the formation and destruction of O<sub>3</sub>, some NO<sub>x</sub> control strategies designed to reduce the highest ambient O<sub>3</sub> concentrations can also result in increases in relatively low ambient O<sub>3</sub> concentrations. As a result of the way the EPA’s epidemiology-based risk assessments were conducted (U.S. EPA, 2014a, Chapter 7), increases estimated in low O<sub>3</sub> concentrations impacted mortality and morbidity risks, leading to the estimated risk increases highlighted

by some commenters. However, while the EPA is confident that reducing the highest ambient O<sub>3</sub> concentrations will result in substantial improvements in public health, including reducing the risk of O<sub>3</sub>-associated mortality, the Agency is far less certain about the public health implications of the changes in relatively low ambient O<sub>3</sub> concentrations (79 FR at 75278/3, 75291/1, and 75308/2). Therefore, reducing precursor emissions to meet a lower O<sub>3</sub> standard is expected to result in important reductions in O<sub>3</sub> concentrations from the part of the air quality distribution where the evidence provides the strongest support for adverse health effects.

Specifically, for area-wide O<sub>3</sub> concentrations at or above 40 ppb,<sup>101</sup> a revised standard with a level of 70 ppb is estimated to reduce the number of premature deaths associated with short-term O<sub>3</sub> concentrations by about 10%, compared to the current standard. In addition, for area-wide concentrations at or above 60 ppb, a revised standard with a level of 70 ppb is estimated to reduce O<sub>3</sub>-associated premature deaths by about 50% to 70%.<sup>102</sup> The EPA views these results, which focus on the portion of the air quality distribution where the evidence indicates the most certainty regarding the occurrence of adverse O<sub>3</sub>-attributable health effects, not only as supportive of the need to revise the current standard (II.B.3, below), but also as showing the benefits of reducing the peak O<sub>3</sub> concentrations associated with air quality distributions meeting the current standard (II.C.4, below).

In addition, even considering risk estimates based on the full distribution of ambient O<sub>3</sub> concentrations (*i.e.*, estimates influenced by decreases in higher concentrations and increases in lower concentrations), the EPA notes that, compared to the current standard, standards with lower levels are estimated to result in overall reductions in mortality risk across the urban study areas evaluated (U.S. EPA, 2014c, Figure 4–10). As discussed above (II.A.2.a, II.A.2.c), analyses in the HREA indicate that these overall risk reductions could understate the actual reductions that

<sup>101</sup> The ISA concludes that there is less certainty in the shape of concentration-response functions for area-wide O<sub>3</sub> concentrations at the lower ends of warm season distributions (*i.e.*, below about 20 to 40 ppb) (U.S. EPA, 2013, section 2.5.4.4).

<sup>102</sup> Available experimental studies provide the strongest evidence for O<sub>3</sub>-induced effects following exposures to O<sub>3</sub> concentrations corresponding to the upper portions of typical ambient distributions. In particular, as discussed above, controlled human exposure studies showing respiratory effects following exposures to O<sub>3</sub> concentrations at or above 60 ppb.

would be experienced by the U.S. population as a whole.

For example, the HREA's national air quality modeling analyses indicate that the HREA urban study areas tend to underrepresent the populations living in areas where reducing NO<sub>x</sub> emissions would be expected to result in decreases in warm season averages of daily maximum 8-hour ambient O<sub>3</sub> concentrations.<sup>103</sup> Given the strong connection between these warm season average O<sub>3</sub> concentrations and risk, risk estimates for the urban study areas are likely to understate the average reductions in O<sub>3</sub>-associated mortality and morbidity risks that would be experienced across the U.S. population as a whole upon reducing NO<sub>x</sub> emissions (U.S. EPA, 2014a, section 8.2.3.2).

In addition, in recognizing that the reductions in modeled NO<sub>x</sub> emissions used in the HREA's core analyses are meant to be illustrative, rather than to imply a particular control strategy for meeting a revised O<sub>3</sub> NAAQS, the HREA also conducted sensitivity analyses in which both NO<sub>x</sub> and VOC emissions reductions were evaluated. In all of the urban study areas evaluated in these analyses, the increases in low O<sub>3</sub> concentrations were smaller for the NO<sub>x</sub>/VOC emission reduction scenarios than the NO<sub>x</sub> only emission reduction scenario (U.S. EPA, 2014a, Appendix 4D, section 4.7). This was most apparent for Denver, Houston, Los Angeles, New York, and Philadelphia. These results suggest that in some locations, optimized emissions reduction strategies could result in larger reductions in O<sub>3</sub>-associated mortality and morbidity than indicated by HREA's core estimates.

Thus, the patterns of estimated mortality and morbidity risks across various air quality scenarios and locations have been evaluated and considered extensively in the HREA and the PA, as well as in the proposal. Epidemiology-based risk estimates have also been considered by CASAC, and those considerations are reflected in CASAC's advice. Specifically, in considering epidemiology-based risk estimates in its review of the REA, CASAC stated that "[a]lthough these estimates for short-term exposure impacts are subject to uncertainty, the CASAC is confident that that the evidence of health effects of O<sub>3</sub>

presented in the ISA and Second Draft HREA in its totality, indicates that there are meaningful reductions in mean, absolute, and relative premature mortality associated with short-term exposures to O<sub>3</sub> levels lower than the current standard" (Frey, 2014a, p. 3). Commenters' views on this issue are not based on new information, but on an interpretation of the analyses presented in the HREA that is different from the EPA's, and CASAC's, interpretation. Given this, the EPA's considerations and conclusions related to this issue, as described in the proposal and as summarized briefly above, remain valid. Therefore, the EPA does not agree with commenters who cited increases in estimated risk in some locations as supporting a conclusion that the current standard should be retained.

For risk estimates of respiratory mortality associated with long-term O<sub>3</sub>, several industry commenters supported placing more emphasis on threshold models, and including these models as part of the core analyses rather than as sensitivity analyses. The EPA agrees with these commenters that an important uncertainty in risk estimates of respiratory mortality associated with long-term O<sub>3</sub> stems from the potential for the existence of a threshold. Based on sensitivity analyses included in the HREA in response to CASAC advice, the existence of a threshold could substantially reduce estimated risks. CASAC discussed this issue at length during its review of the REA and supported the EPA's approach to including a range of threshold models as sensitivity analyses (Frey, 2014a p. 3). Based in part on uncertainty in the existence and identification of a threshold, the HREA concluded that lower confidence should be placed in risk estimates for respiratory mortality associated with long-term O<sub>3</sub> exposures (U.S. EPA, 2014a, section 9.6). This uncertainty was also a key part of the Administrator's rationale for placing only limited emphasis on risk estimates for long-term O<sub>3</sub> exposures. In her final decisions, discussed below (II.B.3, II.C.4.b, II.C.4.c), the Administrator continues to place only limited emphasis on these estimates. The EPA views this approach to considering risk estimates for respiratory mortality as generally consistent with the approach supported by the commenters noted above.

### 3. Administrator's Conclusions on the Need for Revision

This section discusses the Administrator's conclusions related to the adequacy of the public health protection provided by the current

primary O<sub>3</sub> standard, and her final decision that the current standard is not requisite to protect public health with an adequate margin of safety. These conclusions, and her final decision, are based on the Administrator's consideration of the available scientific evidence assessed in the ISA (U.S. EPA, 2013), the exposure/risk information presented and assessed in the HREA (U.S. EPA, 2014a), the consideration of that evidence and information in the PA (U.S. EPA, 2014c), the advice of CASAC, and public comments received on the proposal.

As an initial matter, the Administrator concludes that reducing precursor emissions to achieve O<sub>3</sub> concentrations that meet the current primary O<sub>3</sub> standard will provide important improvements in public health protection, compared to recent air quality. In reaching this conclusion, she notes the discussion in section 3.4 of the PA (U.S. EPA, 2014c). In particular, the Administrator notes that this conclusion is supported by (1) the strong body of scientific evidence indicating a wide range of adverse health outcomes attributable to exposures to O<sub>3</sub> at concentrations commonly found in the ambient air and (2) estimates indicating decreased occurrences of O<sub>3</sub> exposures of concern and decreased O<sub>3</sub>-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.

After reaching the conclusion that meeting the current primary O<sub>3</sub> 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 AQCD support and expand upon the strong body of evidence that, in the last review, indicated a causal relationship between short-term O<sub>3</sub> exposures and respiratory morbidity outcomes (U.S. EPA, 2013, section 2.5). This is the strongest causality finding possible under the ISA's hierarchical system for classifying weight of evidence for causation. In addition, the Administrator notes that the evidence for respiratory health effects attributable to long-term O<sub>3</sub> exposures, including the development of asthma in children, is much stronger than in previous reviews, and the ISA concludes that there is "likely to be" a causal relationship

<sup>103</sup> Specifically, the HREA urban study areas tend to underrepresent populations living in suburban, smaller urban, and rural areas, where reducing NO<sub>x</sub> emissions would be expected to result in decreases in warm season averages of daily maximum 8-hour ambient O<sub>3</sub> concentrations (U.S. EPA, 2014a, section 8.2.3.2).

between such O<sub>3</sub> exposures and adverse respiratory health effects (the second strongest causality finding).

Together, experimental and epidemiologic studies support conclusions regarding a continuum of O<sub>3</sub> 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<sub>3</sub> in reported effects. With regard to mode of action, evidence indicates that the initial key event is the formation of secondary oxidation products in the respiratory tract, that antioxidant capacity may modify the risk of respiratory morbidity associated with O<sub>3</sub> exposure, and that the inherent capacity to quench (based on individual antioxidant capacity) can be overwhelmed, especially with exposure to elevated concentrations of O<sub>3</sub>.

In addition, based on the consistency of findings across studies and the coherence of results from different scientific disciplines, the available evidence indicates that certain populations are at increased risk of experiencing O<sub>3</sub>-related effects, including the most severe effects. These include populations and lifestyles 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).

In considering the O<sub>3</sub> exposure concentrations reported to elicit respiratory effects, as in the proposal, the Administrator agrees with the conclusions of the PA that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following specific O<sub>3</sub> exposures. In particular, she notes that the effects reported in controlled human exposure studies are due solely to O<sub>3</sub> 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, consistent with CASAC advice (Frey, 2014c), she places the most weight on information from controlled human exposure studies in reaching conclusions on the adequacy of the current primary O<sub>3</sub> standard.

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<sub>3</sub> concentrations of 60, 63,<sup>104</sup> 72,<sup>105</sup> 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<sub>3</sub> or higher, with most exposure studies conducted at these higher concentrations. As discussed above (II.A.1), the Administrator 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 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<sub>3</sub> concentrations as low as 60 ppb.

As discussed in her response to public comments above (II.B.2.b.i), and in detail below (II.C.4.b, II.C.4.c), the Administrator concludes that these controlled human exposure studies indicate that adverse effects are likely to occur following exposures to O<sub>3</sub> concentrations below the level of the current standard. The effects observed following such exposures are coherent with the serious health outcomes that have been reported in O<sub>3</sub> epidemiologic studies (*e.g.*, respiratory-related hospital admissions, emergency department visits), and the Administrator judges that such effects have the potential to be important from a public health perspective.

In reaching these conclusions, she particularly notes that the combination of lung function decrements and respiratory symptoms reported to occur in healthy adults following exposures to 72 ppb O<sub>3</sub> meets ATS criteria for an adverse response (II.B.2.b.i, above). In specifically considering the 72 ppb exposure concentration, CASAC noted that “the combination of decrements in FEV<sub>1</sub> 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). In addition, given that the controlled human exposure study reporting these results was conducted in healthy adults,

<sup>104</sup> For a 60 ppb target exposure concentration, Schelegle et al. (2009) reported that the actual 6.6-hour mean exposure concentration was 63 ppb.

<sup>105</sup> For a 70 ppb target exposure concentration, Schelegle et al. (2009) reported that the actual 6.6-hour mean exposure concentration was 72 ppb.

CASAC judged that the adverse combination of lung function decrements and respiratory symptoms “almost certainly occur in some people” (*e.g.*, people with asthma) following exposures to lower O<sub>3</sub> concentrations (Frey, 2014c, p. 6).

While the Administrator is less certain regarding the adversity of the lung function decrements and airway inflammation that have been observed following exposures as low as 60 ppb, as discussed in more detail elsewhere in this preamble (II.B.2.b.i, II.C.4.b, II.C.4.c), she judges that these effects also have the potential to be adverse, and to be of public health importance, particularly if they are experienced repeatedly. With regard to this judgment, she specifically notes the ISA conclusion that, while the airway inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely, continued inflammation could potentially result in adverse effects, including 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, 2013, section 6.2.3). Thus, the Administrator becomes increasingly concerned about the potential for adverse effects at 60 ppb O<sub>3</sub> as the number of exposures increases, though she notes that the available evidence does not indicate a particular number of occurrences of such exposures that would be required to achieve an adverse respiratory effect, and that this number is likely to vary across the population.

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<sub>3</sub> standard. She notes that recent epidemiologic studies provide support, beyond that available in the last review, for associations between short-term O<sub>3</sub> exposures and a wide range of adverse respiratory outcomes (including respiratory-related hospital admissions, emergency department visits, and mortality) and with total mortality. As discussed above in the EPA responses to public comments (II.B.2.b.ii), associations with morbidity and mortality are stronger during the warm or summer months, and remain robust after adjustment for copollutants (U.S. EPA, 2013, Chapter 6).

In considering information from epidemiologic studies within the context of her conclusions on the adequacy of the current standard, the Administrator specifically considers analyses in the PA that evaluate the extent to which O<sub>3</sub> health effect associations have been reported for air quality concentrations likely to be allowed by the current standard. She notes that such analyses can provide insight into the extent to which the current standard would allow the distributions of ambient O<sub>3</sub> concentrations that provided the basis for these health effect associations. While the majority of O<sub>3</sub> epidemiologic studies evaluated in the PA were conducted in areas that would have violated the current standard during study periods, as discussed above (II.B.2.b.ii), the Administrator observes that the study by Mar and Koenig (2009) reported associations between short-term O<sub>3</sub> concentrations and asthma emergency department visits in children and adults in a U.S. location that would have met the current O<sub>3</sub> standard over the entire study period.<sup>106</sup> Based on this, she notes the conclusion from the PA that the current primary O<sub>3</sub> standard would have allowed the distribution of ambient O<sub>3</sub> concentrations that provided the basis for the associations with asthma emergency department visits reported by Mar and Koenig (2009) (U.S. EPA, 2014c, section 3.1.4.2).

In addition, even in some single-city study locations where the current standard was violated (*i.e.*, those evaluated in Silverman and Ito, 2010; Strickland et al., 2010), the Administrator notes that PA analyses of reported concentration-response functions and available air quality data support the occurrence of O<sub>3</sub>-attributable hospital admissions and emergency department visits on subsets of days with virtually all ambient O<sub>3</sub> concentrations below the level of the current standard. PA analyses of study area air quality further support the conclusion that exposures to the ambient O<sub>3</sub> concentrations present in the locations evaluated by Strickland et al. (2010) and Silverman and Ito (2010) could have plausibly resulted in the respiratory-related emergency department visits and hospital admissions reported in these studies (U.S. EPA, 2014c, section 3.1.4.2). The Administrator agrees with the PA

<sup>106</sup> The large majority of locations evaluated in U.S. epidemiologic studies of long-term O<sub>3</sub> would have violated the current standard during study periods, thus providing limited insight into the adequacy of the current standard (U.S. EPA, 2014c, section 3.1.4.3).

conclusion that these analyses indicate a relatively high degree of confidence in reported statistical associations with respiratory health outcomes on days when virtually all monitored 8-hour O<sub>3</sub> concentrations were 75 ppb or below. She further agrees with the PA conclusion that although these analyses do not identify true design values, the presence of O<sub>3</sub>-associated respiratory effects on such days provides insight into the types of health effects that could occur in locations with maximum ambient O<sub>3</sub> concentrations below the level of the current standard.

Compared to the single-city epidemiologic studies discussed above, the Administrator notes additional uncertainty in interpreting the relationships between short-term O<sub>3</sub> air quality in individual study cities and reported O<sub>3</sub> multicity effect estimates. In particular, she judges that the available multicity effect estimates in studies of short-term O<sub>3</sub> do not provide a basis for considering the extent to which reported O<sub>3</sub> health effect associations are influenced by individual locations with ambient O<sub>3</sub> concentrations low enough to meet the current O<sub>3</sub> standard, versus locations with O<sub>3</sub> concentrations that violate this standard.<sup>107</sup> 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<sub>3</sub> associations with respiratory morbidity or premature mortality have been reported in several multicity studies when the majority of study locations (though not all study locations) would have met the current O<sub>3</sub> standard (U.S. EPA, 2014c, section 3.1.4.2).

Looking across the body of epidemiologic evidence, the Administrator thus reaches the conclusion that analyses of air quality in study locations support the occurrence of adverse O<sub>3</sub>-associated effects at ambient O<sub>3</sub> concentrations that met, or are likely to have met, the current standard. She further concludes that the strongest support for this conclusion comes from single-city studies of

<sup>107</sup> As noted in the proposal (II.E.4.d), this uncertainty applies specifically to interpreting air quality analyses within the context of multicity effect estimates for short-term O<sub>3</sub> concentrations, where effect estimates for individual study cities are not presented (as is the case for the key O<sub>3</sub> 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). This specific uncertainty does not apply to multicity epidemiologic studies of long-term O<sub>3</sub> concentrations, where multicity effect estimates are based on comparisons across cities. For example, see discussion of study by Jerrett et al. (2009) in the PA (U.S. EPA, 2014c, section 3.1.4.3).

respiratory-related hospital admissions and emergency department visits associated with short-term O<sub>3</sub> concentrations, with some support also from multicity studies of morbidity or mortality.

Taken together, the Administrator concludes that the scientific evidence from controlled human exposure and epidemiologic studies calls into question the adequacy of the public health protection provided by the current standard. In reaching this conclusion, she particularly notes that the current standard level is higher than the lowest O<sub>3</sub> exposure concentration shown to result in the adverse combination of lung function decrements and respiratory symptoms (*i.e.*, 72 ppb), and that CASAC concluded that such effects “almost certainly occur in some people” following exposures to O<sub>3</sub> concentrations below 72 ppb (Frey, 2014c, p. 6). While she also notes that the current standard level is well-above the lowest O<sub>3</sub> exposure concentration shown to cause respiratory effects (*i.e.*, 60 ppb), she has less confidence that the effects observed at 60 ppb are adverse (discussed in II.B.2.b.i, II.C.4.b, II.C.4.c). She further considers these effects, and the extent to which the current primary O<sub>3</sub> standard could protect against them, within the context of quantitative analyses of O<sub>3</sub> exposures (discussed below). With regard to the available epidemiologic evidence, the Administrator notes PA analyses of O<sub>3</sub> air quality indicating that, while most O<sub>3</sub> epidemiologic studies reported health effect associations with ambient O<sub>3</sub> concentrations that violated the current standard, a small number of single-city U.S. studies support the occurrence of asthma-related hospital admissions and emergency department visits at ambient O<sub>3</sub> concentrations below the level of the current standard, including one study with air quality that would have met the current standard during the study period. Some support for such O<sub>3</sub> associations is also provided by multicity studies of morbidity or mortality. The Administrator further judges that the biological plausibility of associations with clearly adverse morbidity effects is supported by the evidence noted above from controlled human exposure studies conducted at, or in some cases below, typical warm-season ambient O<sub>3</sub> concentrations.

Beyond her consideration of the scientific evidence, the Administrator also considers the results of the HREA exposure and risk analyses in reaching final conclusions regarding the adequacy of the current primary O<sub>3</sub> standard. In doing so, consistent with

her consideration of the evidence, she focuses primarily on quantitative analyses based on information from controlled human exposure studies (*i.e.*, exposures of concern and risk of O<sub>3</sub>-induced FEV<sub>1</sub> decrements). Consistent with the considerations in the PA, and with CASAC advice (Frey, 2014c), she particularly focuses on exposure and risk estimates in children.<sup>108</sup> As discussed in the HREA and PA (and II.B, above), the patterns of exposure and risk estimates across urban study areas, across years, and across air quality scenarios are similar in children and adults though, because children spend more time being physically active outdoors and are more likely to experience the types of O<sub>3</sub> exposures shown to cause respiratory effects, larger percentages of children are estimated to experience exposures of concern and O<sub>3</sub>-induced FEV<sub>1</sub> decrements. Children also have intrinsic risk factors that make them particularly susceptible to O<sub>3</sub>-related effects (*e.g.*, higher ventilation rates relative to lung volume) (U.S. EPA, 2013, section 8.3.1.1; see section II.A.1.d above). In focusing on exposure and risk estimates in children, 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. She judges that, to the extent the primary O<sub>3</sub> standard provides appropriate protection for children, it will also do so for adult populations,<sup>109</sup> given the larger exposures and intrinsic risk factors in children.

In first considering estimates of exposures of concern, the Administrator considers the extent to which estimates indicate that the current standard limits population exposures to the broader range of O<sub>3</sub> concentrations shown in controlled human exposure studies to cause respiratory effects. In doing so, she focuses on estimates of O<sub>3</sub>

exposures of concern at or above the benchmark concentrations of 60, 70, and 80 ppb. She notes that the current O<sub>3</sub> standard can provide some protection against exposures of concern to a range of O<sub>3</sub> concentrations, including concentrations below the standard level, given that (1) with the current fourth-high form, most days will have concentrations below the standard level and that (2) exposures of concern depend on both the presence of relatively high ambient O<sub>3</sub> concentrations and on activity patterns in the population that result in exposures to such high concentrations while at an elevated ventilation rate (discussed in detail below, II.C.4.b and II.C.4.c).

In considering estimates of O<sub>3</sub> exposures of concern allowed by the current standard, she 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 (II.B.2.b.i, II.C.4.b, II.C.4.c, below), she becomes increasingly concerned about the potential for adverse responses as the number of occurrences increases.<sup>110</sup> In particular, as discussed above with regard to inflammation, she notes that the types of lung injury shown to occur following exposures to O<sub>3</sub> concentrations from 60 to 80 ppb, particularly if experienced repeatedly, provide a mode of action by which O<sub>3</sub> 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 exposures for the 70 and 80 ppb benchmarks.

In considering estimates of exposures of concern, the Administrator first notes that if the 15 urban study areas evaluated in the HREA were to just meet the current O<sub>3</sub> 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, based on exposure estimates averaged over the years of analysis, though up to about 2% would be estimated to experience such exposures in the worst-case year and location (*i.e.*, year and location with the largest

exposure estimates).<sup>111</sup> Although the Administrator is less concerned about single occurrences of exposures of concern, she notes that even single occurrences could cause adverse effects in some people, particularly for the 70 and 80 ppb benchmarks.<sup>112</sup> As illustrated in Table 1 (above), the current standard could allow up to about 3% of children to experience one or more exposures of concern at or above 70 ppb, averaged over the years of analysis, and up to about 8% in the worst-case year and location. In addition, in the worst-case year and location, the current standard could allow about 1% of children to experience at least one exposure of concern at or above 80 ppb, the highest benchmark evaluated.

While the Administrator has less confidence in the adversity of the effects observed following exposures to 60 ppb O<sub>3</sub> (II.B.2.b.i, II.C.4.b, II.C.4.c), particularly for single exposures, she judges that the potential for adverse effects increases as the number of exposures of concern increases. With regard to the 60 ppb benchmark, she particularly notes that the current standard is estimated to allow approximately 3 to 8% of children in urban study areas, including approximately 3 to 8% of asthmatic children, to experience two or more exposures of concern to O<sub>3</sub> concentrations at or above 60 ppb, based on estimates averaged over the years of analysis. To provide some perspective on the average percentages estimated, the Administrator notes that they correspond to almost 900,000 children in urban study areas, including about 90,000 asthmatic children. Nationally, if the current standard were to be just met, the number of children experiencing such exposures would be larger.

Based on her consideration of these estimates within the context of her judgments on adversity, as discussed in her responses to public comments (II.B.2.b.i, II.C.4.b), the Administrator concludes that the exposures projected to remain upon meeting the current standard can reasonably be judged to be important from a public health perspective. In particular, given that the average percent of children estimated to experience two or more exposures of concern for the 60 ppb benchmark approaches 10% in some areas, even based on estimates averaged over the

<sup>108</sup> She focuses on estimates for all children and estimates for children with asthma, noting that exposure and risk estimates for these groups are virtually indistinguishable in terms of the percent estimated to experience exposures of concern or O<sub>3</sub>-induced FEV<sub>1</sub> decrements (U.S. EPA, 2014c, sections 3.2 and 4.4.2).

<sup>109</sup> As noted below (II.C.4.2), this includes populations of highly active adults, such as outdoor workers. Limited sensitivity analyses in the HREA indicate that when diaries were selected to mimic exposures that could be experienced by outdoor workers, the percentages of modeled individuals 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 urban study areas and years with the largest exposure estimates (U.S. EPA, 2014, section 5.4.3.2, Figure 5–14).

<sup>110</sup> Not all people who experience an exposure of concern will experience an adverse effect (even members of at-risk populations). For the endpoints evaluated in controlled human exposure studies, the number of those experiencing exposures of concern who will experience adverse effects cannot be reliably quantified.

<sup>111</sup> Virtually no children in those areas would be estimated to experience two or more exposures of concern at or above 80 ppb.

<sup>112</sup> That is, adverse effects are a possible outcome of single exposures of concern at/above 70 or 80 ppb, though the available information is not sufficient to estimate the likelihood of such effects.



years of the analysis, she concludes that the current standard does not incorporate an adequate margin of safety against the potentially adverse effects that can occur following repeated exposures at or above 60 ppb. Although she has less confidence that the effects observed at 60 ppb are adverse, compared to the effects at and above 72 ppb, she judges that this approach to considering the results for the 60 ppb benchmark is appropriate given CASAC advice, which clearly focuses the EPA on considering the effects observed at 60 ppb (Frey, 2014c) (II.C.4.b, II.C.4.c below).<sup>113</sup> This approach to considering estimated exposures of concern is consistent with setting standards that provide some safeguard against dangers to human health that are not fully certain (*i.e.*, standards that incorporate an adequate margin of safety) (See, *e.g.*, *State of Mississippi*, 744 F. 3d at 1353).

In addition to estimated exposures of concern, the Administrator also considers HREA estimates of the risk of O<sub>3</sub>-induced FEV<sub>1</sub> decrements  $\geq 10$  and 15%. In doing so, she particularly notes CASAC advice that “estimation of FEV<sub>1</sub> decrements of  $\geq 15\%$  is appropriate as a scientifically relevant surrogate for adverse health outcomes in active healthy adults, whereas an FEV<sub>1</sub> decrement of  $\geq 10\%$  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<sub>3</sub>-induced lung function decrements could be adverse for some people, as discussed above (II.B.1), she agrees with the judgment in past reviews that a more general consensus view of the potential adversity of such decrements emerges as the frequency of occurrences increases. Therefore, as in the proposal, the Administrator focuses primarily on the estimates of two or more O<sub>3</sub>-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<sub>3</sub>-induced lung function decrements  $\geq 15\%$ , and to allow about 8 to 12% of children (corresponding to about 180,000 asthmatic children) to experience two or more O<sub>3</sub>-induced lung function decrements  $\geq 10\%$ .

In further considering the HREA results, the Administrator considers the

<sup>113</sup> Though this advice is less clear regarding the adversity of effects at 60 ppb than CASAC's advice regarding the adversity of effects at 72 ppb (II.C.4.b, II.C.4.c).

epidemiology-based risk estimates. As discussed in the proposal, 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 risk estimates, as discussed in the proposal and above in the EPA's responses to public comments (II.B.2.b.iii), the Administrator focuses on the risks associated with O<sub>3</sub> concentrations in the upper portions of ambient distributions. In doing so, she notes the increasing uncertainty associated with the shapes of concentration-response curves for O<sub>3</sub> concentrations in the lower portions of ambient distributions and the evidence from controlled human exposure studies, which provide the strongest support for O<sub>3</sub>-induced effects following exposures to O<sub>3</sub> concentrations corresponding to the upper portions of typical ambient distributions (*i.e.*, 60 ppb and above). Even when considering only area-wide O<sub>3</sub> concentrations from the upper portions of seasonal distributions (*i.e.*,  $\geq 40$ , 60 ppb, Table 3 in the proposal), the Administrator notes that the general magnitude of mortality risk estimates suggests the potential for a substantial number of O<sub>3</sub>-associated deaths and adverse respiratory events to occur nationally, even when the current standard is met (79 FR 75277 and II.B.2.c.iii above).

In addition to the evidence and exposure/risk information discussed above, the Administrator also takes note of the CASAC advice in the current review, in the 2008 review and decision establishing the current standard, and in the 2010 reconsideration of the 2008 decision. 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<sub>3</sub> Panel likewise recommended revision of the current standard to one with a lower level due to the lack of protectiveness of the current standard. 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; Frey and Samet, 2012).

In consideration of all of the above, the Administrator concludes that the current primary O<sub>3</sub> standard 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. This decision is based on the Administrator's 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 such that it is not appropriate, within the meaning of section 109(d)(1) of the CAA, to retain the current standard. With regard to the evidence, she particularly notes that the current standard level is higher than the lowest O<sub>3</sub> exposure concentration shown to result in the adverse combination of lung function decrements and respiratory symptoms (*i.e.*, 72 ppb), and also notes CASAC's advice that at-risk groups (*e.g.*, people with asthma) could experience adverse effects following exposure to lower concentrations. In addition, while the Administrator is less certain about the adversity of the effects that occur following lower exposure concentrations, she judges that recent controlled human exposure studies at 60 ppb provide support for a level below 75 ppb in order to provide an increased margin of safety, compared to the current standard, against effects with the potential to be adverse, particularly if they are experienced repeatedly. With regard to O<sub>3</sub> epidemiologic studies, she notes that while most available studies reported health effect associations with ambient O<sub>3</sub> concentrations that violated the current standard, a small number provide support for the occurrence of adverse respiratory effects at ambient O<sub>3</sub> concentrations below the level of the current standard.<sup>114</sup>

Based on the analyses in the HREA, the Administrator 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. In particular, this conclusion is based on her judgment that it is appropriate to set a standard that would be expected to eliminate, or almost eliminate, exposures of concern at or above 70 and 80 ppb. In addition, given that the average percent of children estimated to experience two or more exposures of concern for the 60 ppb benchmark approaches 10% in some urban study areas, the Administrator concludes that the current standard does not incorporate an adequate margin of safety

<sup>114</sup> 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. See *e.g.* *Mississippi*, 744 F. 3d at 1345; *American Farm Bureau*, 559 F. 3d at 525–26.



against the potentially adverse effects that could occur following repeated exposures at or above 60 ppb. Beyond estimated exposures of concern, the Administrator concludes that the HREA risk estimates (FEV<sub>1</sub> risk estimates, mortality risk estimates) further support a conclusion that the O<sub>3</sub>-associated health effects estimated to remain upon just meeting the current standard are an issue of public health importance on a broad national scale. Thus, she concludes that O<sub>3</sub> exposure and risk estimates, when taken together, support a conclusion that the exposures and health risks associated with just meeting the current standard can reasonably be judged important from a public health perspective, such that the current standard is not sufficiently protective and does not incorporate an adequate margin of safety.

In the next section, the Administrator considers what revisions are appropriate in order to set a standard that is requisite to protect public health with an adequate margin of safety.

### C. Conclusions on the Elements of a Revised Primary Standard

Having reached the conclusion that the current O<sub>3</sub> standard is not requisite to protect public health with an adequate margin of safety, based on the currently available scientific evidence and exposure/risk information, 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 conclusions on the elements of the primary standard 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 public comments. The sections below discuss the evidence and exposure/risk information, CASAC advice and public input, and the Administrator's proposed conclusions, for the major elements of the NAAQS: Indicator (II.C.1), averaging time (II.C.2), form (II.C.3), and level (II.C.4).

#### 1. Indicator

In the 2008 review, the EPA focused on O<sub>3</sub> 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<sub>3</sub> plays a key role has been highlighted, no alternatives to O<sub>3</sub> have been advanced as being a more appropriate indicator for ambient

photochemical oxidants. More specifically, the ISA noted that O<sub>3</sub> is the only photochemical oxidant (other than NO<sub>2</sub>) that is routinely monitored and for which a comprehensive database exists (U.S. EPA, 2013, section 3.6). Data for other photochemical oxidants (e.g., peroxyacetyl nitrate, hydrogen peroxide, 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<sub>3</sub> (U.S. EPA, 2013, 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<sub>3</sub> 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<sub>3</sub> alone (U.S. EPA, 2014c, section 4.1). That is, since the precursor emissions that lead to the formation of O<sub>3</sub> generally also lead to the formation of other photochemical oxidants, measures leading to reductions in population exposures to O<sub>3</sub> 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 reached the proposed conclusion that O<sub>3</sub> remains the most appropriate indicator for a standard meant to provide protection against photochemical oxidants.<sup>115</sup>

The EPA received very few comments on the indicator of the primary standard. Those who did comment supported the proposed decision to retain O<sub>3</sub> as the indicator, noting the rationale put forward in the preamble to the proposed rule. These commenters generally expressed support for retaining the current indicator in conjunction with retaining other elements of the current standard, such as the averaging time and form. After considering the available evidence, CASAC advice, and public comments, the Administrator concludes that O<sub>3</sub> remains the most appropriate indicator

<sup>115</sup> The DC Circuit upheld the use of O<sub>3</sub> 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).

for a standard meant to provide protection against photochemical oxidants. Therefore, she is retaining O<sub>3</sub> as the indicator for the primary standard in this final rule.

#### 2. Averaging Time

The EPA established the current 8-hour averaging time<sup>116</sup> for the primary O<sub>3</sub> 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 adverse respiratory effects and 6- to 8-hour O<sub>3</sub> concentrations (62 FR 38861). The EPA also noted that a standard with a maximum 8-hour averaging time is likely to provide substantial protection against respiratory effects associated with 1-hour peak O<sub>3</sub> concentrations. The EPA reached similar conclusions in the last O<sub>3</sub> NAAQS review and thus, the EPA retained the 8-hour averaging time in 2008.

In reaching a proposed conclusion on averaging time in the current review, the Administrator considered the extent to which the available evidence continues to support the appropriateness of a standard with an 8-hour averaging time (79 FR 75292). Specifically, the Administrator considered 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<sub>3</sub> exposures. These considerations from the proposal are summarized below in sections II.C.2.a (short-term) and II.C.2.b (long-term). Section II.C.2.c summarizes the Administrator's proposed decision on averaging time. Section II.C.2.d discusses comments received on averaging time. Section II.C.2.e presents the Administrator's final decision regarding averaging time.

##### a. Short-Term

As an initial consideration with respect to the most appropriate averaging time for the O<sub>3</sub> NAAQS, in the proposal the Administrator noted that the strongest evidence for O<sub>3</sub>-associated health effects is for respiratory effects following short-term exposures. More specifically, the Administrator noted the ISA conclusion that the evidence is "sufficient to infer a causal relationship" between short-term O<sub>3</sub> exposures and respiratory effects. The ISA also judges that for short-term O<sub>3</sub> exposures, the evidence indicates "likely to be causal" relationships with

<sup>116</sup> This 8-hour averaging time reflects daily maximum 8-hour average O<sub>3</sub> concentrations.

both cardiovascular effects and mortality (U.S. EPA, 2013, section 2.5.2). Therefore, as in past reviews, the Administrator noted that the strength of the available scientific evidence provides strong support for a standard that protects the public health against short-term exposures to O<sub>3</sub>.

In first considering the level of support available for specific short-term averaging times, the Administrator noted in the proposal 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 airway hyperresponsiveness) occur in healthy adults following 6.6-hour exposures to O<sub>3</sub> (U.S. EPA, 2013, 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<sub>3</sub> exposure concentrations and at more moderate levels of exertion.

The Administrator also noted in the proposal the strength of evidence from epidemiologic studies that evaluated a wide variety of populations (e.g., including at-risk lifestyles and populations, such as children and people with asthma, respectively). A number of different averaging times have been used in O<sub>3</sub> 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-hour max), and the 24-hour average. These studies are assessed in detail in Chapter 6 of the ISA (U.S. EPA, 2013). 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<sub>3</sub> risk estimates when using a 24-hour average exposure metric” (U.S. EPA, 2013, section 2.5.4.2; p. 2–31). For single- and multi-day average O<sub>3</sub> concentrations, lung function decrements were associated with 1-hour max, 8-hour max, and 24-hour average ambient O<sub>3</sub> concentrations, with no strong difference in the consistency or magnitude of association among the averaging times (U.S. EPA, 2013, p. 6–71). Similarly, in studies of short-term exposure to O<sub>3</sub> 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, 2013, p. 6–253). Thus, the Administrator noted 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, in the proposal the Administrator concluded that an 8-hour averaging time remains appropriate for addressing health effects associated with short-term exposures to ambient O<sub>3</sub>. An 8-hour 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<sub>3</sub> concentrations below the level of the current standard. In addition, epidemiologic studies provide evidence for health effect associations with 8-hour O<sub>3</sub> concentrations, as well as with 1-hour and 24-hour concentrations. As in previous reviews, the Administrator noted 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<sub>3</sub> exposures indicates that there is “likely to be a causal relationship” with respiratory effects (U.S. EPA, 2013, 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<sub>3</sub>.

In considering this issue in the 2008 review of the O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> in terms of seasonal averages of daily maximum 1-hour or 8-hour concentrations.

As an initial consideration, in the proposal the Administrator noted the risk results from the HREA for respiratory mortality associated with long-term O<sub>3</sub> 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<sub>3</sub> concentrations based on the seasonal averages of 1-hour daily maximum O<sub>3</sub> concentrations evaluated in the study by Jerrett *et al.* (2009) (U.S. EPA, 2014a, chapter 7).<sup>117</sup> 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<sub>3</sub> concentrations, respiratory mortality risks are estimated to be reduced further in urban study areas. This analysis indicates that an O<sub>3</sub> 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<sub>3</sub> concentrations.

In further considering the study by Jerrett *et al.* (2009), in the proposal the Administrator noted the PA comparison of long-term O<sub>3</sub> 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<sub>3</sub> concentrations, and can maintain those O<sub>3</sub> 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).

<sup>117</sup> Though the Administrator also notes important uncertainties associated with these risk estimates, as discussed in section II.C.3.b of the proposal.

The Administrator also noted in the proposal that the HREA conducted analyses evaluating the impacts of reducing regional NO<sub>x</sub> emissions on the seasonal averages of daily maximum 8-hour O<sub>3</sub> concentrations. Seasonal averages of 8-hour daily max O<sub>3</sub> concentrations reflect long-term metrics that have been reported to be associated with respiratory morbidity effects in several recent O<sub>3</sub> epidemiologic studies (e.g., Islam *et al.*, 2008; Lin *et al.*, 2008a, 2008b; Salam *et al.*, 2009). The HREA analyses indicate that the large majority of the U.S. population lives in locations where reducing NO<sub>x</sub> emissions would be expected to result in decreases in seasonal averages of daily max 8-hour ambient O<sub>3</sub> concentrations (U.S. EPA, 2014a, chapter 8). Thus, consistent with the respiratory mortality risk estimates noted above, these analyses suggest that reductions in O<sub>3</sub> precursor emissions in order to meet a standard with an 8-hour averaging time would also be expected to reduce the long-term O<sub>3</sub> concentrations that have been reported in recent epidemiologic studies to be associated with respiratory morbidity.

#### c. Administrator's Proposed Conclusion on Averaging Time

In the proposal the Administrator noted that, when taken together, the analyses summarized above indicate that a standard with an 8-hour averaging time, coupled with the current fourth-high form and an appropriate level, would be expected to provide appropriate protection against the short- and long-term O<sub>3</sub> 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 proposed to retain the current 8-hour averaging time, and not to set an additional standard with a different averaging time.

#### d. Comments on Averaging Time

Most public commenters did not address the issue of whether the EPA should consider additional or alternative averaging times. Of those who did address this issue, some commenters representing state agencies or industry groups agreed with the

proposed decision to retain the current 8-hour averaging time, generally noting the supportive evidence discussed in the preamble to the proposed rule. In contrast, several medical organizations and environmental groups questioned the degree of health protection provided by a standard based on an 8-hour averaging time. For example, one group asserted that “[a]veraging over any time period, such as 8 hours, is capable of hiding peaks that may be very substantial if they are brief enough.”

The EPA agrees with these commenters that an important issue in the current review is the appropriateness of using a standard with an 8-hour averaging time to protect against adverse health effects that are attributable to a wide range of O<sub>3</sub> exposure durations, including those shorter and longer than 8 hours. This is an issue that has been thoroughly evaluated by the EPA in past reviews, as well as in the current review.

The 8-hour O<sub>3</sub> NAAQS was originally set in 1997, as part of revising the then-existing standard with its 1-hour averaging time, and was retained in the review completed in 2008 (73 FR 16472). In both of these reviews, several lines of evidence and information provided support for an 8-hour averaging time rather than a shorter averaging time. For example, substantial health evidence demonstrated associations between a wide range of respiratory effects and 6- to 8-hour exposures to relatively low O<sub>3</sub> concentrations (*i.e.*, below the level of the 1-hour O<sub>3</sub> NAAQS in place prior to the review completed in 1997). A standard with an 8-hour averaging time was determined to be more directly associated with health effects of concern at lower O<sub>3</sub> concentrations than a standard with a 1-hour averaging time. In addition, results of quantitative analyses showed that a standard with an 8-hour averaging time can effectively limit both 1- and 8-hour exposures of concern, and that an 8-hour averaging time results in a more uniformly protective national standard than a 1-hour averaging time. In past reviews, CASAC has agreed that an 8-hour averaging time is appropriate.

In reaching her proposed decision to retain the 8-hour averaging time in the current review, the Administrator again considered the body of evidence for adverse effects attributable to a wide range of O<sub>3</sub> exposure durations, including studies specifically referenced by public commenters who questioned the protectiveness of a standard with an 8-hour averaging time. For example, as noted above a substantial body of health effects evidence from controlled human

exposure studies demonstrates that a wide range of respiratory effects occur in healthy adults following 6.6-hour exposures to O<sub>3</sub> (U.S. EPA, 2013, 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<sub>3</sub> exposure concentrations and at more moderate levels of exertion. The Administrator also noted the strength of evidence from epidemiologic studies that evaluated a number of different averaging times, with the most common being the maximum 1-hour concentration within a 24-hour period (1-hour max), the maximum 8-hour average concentration within a 24-hour period (8-hour max), and the 24-hour average. 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 (U.S. EPA, 2013, section 2.5.4.2; p. 2–31). For single- and multi-day average O<sub>3</sub> concentrations, lung function decrements were associated with 1-hour max, 8-hour max, and 24-hour average ambient O<sub>3</sub> concentrations, with no strong difference in the consistency or magnitude of association among the averaging times (U.S. EPA, 2013, p. 6–71). Similarly, in studies of short-term exposure to O<sub>3</sub> 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, 2013, p. 6–253). Thus, the epidemiologic evidence does not provide a strong basis for distinguishing between the appropriateness of 1-hour, 8-hour, and 24-hour averaging times.

In addition, quantitative exposure and risk analyses in the HREA are based on an air quality adjustment approach that estimates hourly O<sub>3</sub> concentrations, and on scientific studies that evaluated health effects attributable to a wide range of O<sub>3</sub> exposure durations. For example, the risk of lung function decrements is estimated using a model based on controlled human exposure studies with exposure durations ranging from 2 to 7.6 hours (U.S. EPA, 2013, section 6.2.1.1). Epidemiology-based risk estimates are based on studies that reported health effect associations with short-term ambient O<sub>3</sub> concentrations ranging from 1-hour to 24-hours and with long-term seasonal average concentrations (U.S. EPA, 2014a, Table 7–2). Thus, the HREA estimated health

risks associated with a wide range of O<sub>3</sub> exposure durations and the Administrator's conclusions on averaging time in the current review are based, in part, on consideration of these estimates.

When taken together, the evidence and analyses indicate that a standard with an 8-hour averaging time, coupled with the current fourth-highest form and an appropriate level, would be expected to provide appropriate protection against the short- and long-term O<sub>3</sub> concentrations that have been reported to be associated with respiratory morbidity and mortality. The CASAC agreed with this, stating the following (Frey, 2014c, p. 6):

The current 8-hour averaging time is justified by the combined evidence from epidemiologic and clinical studies referenced in Chapter 4. Results from clinical studies, for example, show a wide range of respiratory effects in healthy adults following 6.6 hours of exposure to ozone, including pulmonary function decrements, increases in respiratory symptoms, lung inflammation, lung permeability, decreased lung host defense, and airway hyperresponsiveness. These findings are supported by evidence from epidemiological studies that show causal associations between short-term exposures of 1, 8 and 24-hours and respiratory effects and "likely to be causal" associations for cardiovascular effects and premature mortality. The 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.

Given all of the above, the EPA disagrees with commenters who question the protectiveness of an O<sub>3</sub> standard with an 8-hour averaging time, particularly for an 8-hour standard with the revised level of 70 ppb that is being established in this review, as discussed below (II.C.4).

#### e. Administrator's Final Decision Regarding Averaging Time

In considering the evidence and information summarized in the proposal and discussed in detail in the ISA, HREA, and PA; CASAC's views; and public comments, the Administrator concludes that a standard with an 8-hour averaging time can effectively limit health effects attributable to both short- and long-term O<sub>3</sub> exposures. As was the case in the proposal, this final conclusion is based on (1) the strong evidence that continues to support the importance of protecting public health against short-term O<sub>3</sub> exposures (e.g., ≤ 1-hour to 24-hour) and (2) analyses in the HREA and PA supporting the conclusion that the current 8-hour averaging time can effectively limit long-term O<sub>3</sub> exposures. Furthermore,

the Administrator observes that the CASAC Panel agreed with the choice of averaging time (Frey, 2014c). Therefore, in the current review, the Administrator concludes that it is appropriate to retain the 8-hour averaging time and to not set a separate standard with a different averaging time in this final rule.

#### 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 fourth-highest 8-hour daily maximum O<sub>3</sub> concentrations. Section II.C.3.a below summarizes the basis for the current form. Section II.C.3.b discusses the Administrator's proposed decision to retain the current form. Section II.C.3.c discusses public comments received on the form of the primary standard. Section II.C.3.d discusses the Administrator's final decision on form.

##### a. Basis for the Current Form

The EPA established the current form of the primary O<sub>3</sub> NAAQS in 1997 (62 FR 38856). Prior to that time, the standard had a "1-expected-exceedance" form.<sup>118</sup> An advantage of the current concentration-based form recognized in the 1997 review is that such a form better reflects the continuum of health effects associated with increasing ambient O<sub>3</sub> concentrations. Unlike an expected exceedance form, a concentration-based form gives proportionally more weight to years when 8-hour O<sub>3</sub> concentrations are well above the level of the standard than years when 8-hour O<sub>3</sub> concentrations are just above the level of the standard.<sup>119</sup> The EPA judged it

<sup>118</sup> 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.

<sup>119</sup> As discussed (61 FR 65731), this is because with an exceedance-based form, days on which the ambient O<sub>3</sub> concentration is well above the level of the standard are given equal weight to those days on which the O<sub>3</sub> 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<sub>3</sub> concentrations occur would weigh proportionally more than days with lower O<sub>3</sub> concentrations since

appropriate to give more weight to higher O<sub>3</sub> concentrations, given that available health evidence indicated a continuum of effects associated with exposures to varying concentrations of O<sub>3</sub>, and given that the extent to which public health is affected by exposure to ambient O<sub>3</sub> is related to the actual magnitude of the O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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). The EPA also considered 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.<sup>120</sup> 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<sub>3</sub> seasons relative to locations with shorter O<sub>3</sub> seasons. Thus, in the 2008 review, the EPA concluded that a form based on the nth-highest maximum O<sub>3</sub> concentration would more effectively ensure that people who live in areas

the actual concentrations are used directly to calculate whether the standard is met or violated.

<sup>120</sup> See *American Trucking Ass'n v. EPA*, 283 F.3d at 374-75 (less stable implementation programs may be less effective and would thereby provide less public health protection; EPA may therefore legitimately consider programmatic stability in determining the form of a NAAQS).

with different length O<sub>3</sub> 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, the Administrator concluded that a fourth-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 (fourth-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<sub>3</sub>, for example, he noted the importance of a form insulated from the impacts of extreme meteorological events that are conducive to O<sub>3</sub> 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 fourth-high form “provides a stable target for implementing programs to improve air quality” (*id.* at 16475).

#### b. Proposed Decision on Form

In the proposal for the current review, the Administrator considered the extent to which newly available information provides support for the current form (79 FR 75293). In so doing, she took note of the conclusions of prior reviews summarized above. She recognized the value of an nth-high statistic over that of an expected exceedance or percentile-based form in the case of the O<sub>3</sub> standard, for the reasons summarized above. The Administrator additionally took note of the importance of stability in implementation to achieving the level of protection specified by the NAAQS. Specifically, she noted that to the extent areas engaged in implementing the O<sub>3</sub> 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 considered particularly the findings from prior reviews with regard to the use of the nth-high metric. As noted above, the EPA selected the fourth-highest daily maximum, recognizing 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. In the proposal the Administrator concluded that the currently available evidence and information do not call into question these conclusions from previous reviews. In reaching this initial conclusion, the Administrator noted that CASAC concurred that the O<sub>3</sub> 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 fourth-high form, coupled with a level lower than 75 ppb 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 proposed to retain the current fourth-highest daily maximum form for an O<sub>3</sub> standard with an 8-hour averaging time and a revised level.

#### c. Public Comments on Form

Several commenters focused on the stability of the standard to support their positions regarding form. Some industry associations and state agencies support changing to a form that would allow a larger number of exceedances of the standard level than are allowed by the current fourth-high form. In some cases, these commenters argued that a standard allowing a greater number of exceedances would provide the same degree of public health protection as the current standard. Some commenters advocated a percentile-based form, such as the 98th percentile. These commenters cited a desire for consistency with short-term standards for other criteria pollutants (*e.g.*, PM<sub>2.5</sub>,

NO<sub>2</sub>), as well as a desire to allow a greater number of exceedances of the standard level, thus making the standard less sensitive to fluctuations in background O<sub>3</sub> concentrations and to extreme meteorological events.

Other commenters submitted analyses purporting to indicate that a fourth-high form provides only a small increase in stability, relative to forms that allow fewer exceedances of the standard level (*i.e.*, first-high, second-high). These commenters also called into question the degree of health protection achieved by a standard with a fourth-high form and a level in the proposed range (*i.e.*, 65 to 70 ppb). They pointed out that a fourth-high form will, by definition, allow 3 days per year, on average, with 8-hour O<sub>3</sub> concentrations above the level of the standard. Commenters further stated that “[i]f ozone levels on these peak days are appreciably higher than on the fourth-highest day, given EPA’s acknowledged concerns regarding single or multiple (defined by EPA as 2 or more) exposures to elevated ozone concentrations, EPA must account for the degree of under-protection in setting the level of the NAAQS” (*e.g.*, ALA *et al.*, p. 138).

For the reasons discussed in the proposal, and summarized above, the EPA disagrees with commenters who supported a percentile-based form, such as the 98th percentile, for the O<sub>3</sub> NAAQS. As noted above, a percentile-based statistic would not be effective in ensuring the same degree of public health protection across the country. Rather, a percentile-based form would allow more days with higher air quality values in locations with longer O<sub>3</sub> seasons relative to locations with shorter O<sub>3</sub> seasons. Thus, as in the 2008 review, in the current review the EPA concludes that a form based on the nth-highest maximum O<sub>3</sub> concentration would more effectively ensure that people who live in areas with different length O<sub>3</sub> seasons receive the same degree of public health protection.

In considering various nth-high values, as in past reviews (*e.g.*, 73 FR 16475, March 27, 2008), the EPA recognizes that there is not a clear health-based threshold for selecting a particular nth-highest daily maximum form. Rather, the primary consideration is the adequacy of the public health protection provided by the combination of all of the elements of the standard, including the form. Environmental and public health commenters are correct that a standard with the current fourth-high form will allow 3 days per year, on average, with 8-hour O<sub>3</sub> concentrations higher than the standard level. However, the EPA disagrees with these

commenters' assertion that using a fourth-high form results in a standard that is under-protective. The O<sub>3</sub> exposure and risk estimates that informed the Administrator's consideration of the degree of public health protection provided by various standard levels were based on air quality that "just meets" various standards with the current 8-hour averaging time and fourth-high, 3-year average form (U.S. EPA, 2014a, section 4.3.3). Therefore, air quality adjusted to meet various levels of the standard with the current form and averaging time will include days with concentrations above the level of the standard, and these days contribute to exposure and risk estimates. In this way, the Administrator has reasonably considered the public health protection provided by the combination of all of the elements of the standard, including the fourth-high form.

In past reviews, EPA selected the fourth-highest daily maximum form 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 ongoing implementation programs. As noted above, some commenters submitted analyses suggesting that a fourth-high form provides only a small increase in stability, relative to a first- or second-high form. The EPA has conducted analyses of ambient O<sub>3</sub> monitoring data to further consider these commenters' assertions regarding stability. The EPA's analyses of nth-high concentrations ranging from first-high to fifth-high have been summarized in a memo to the docket (Wells, 2015a). Consistent with commenters' analyses, Wells (2015a) indicates a progressive decrease in the variability of O<sub>3</sub> concentrations, and an increase in the stability of those concentrations, as "n" increases. Based on these analyses, there is no clear threshold for selecting a particular nth-high form based on stability alone. Rather, as in past reviews, the decision on form in this review focuses first and foremost on the Administrator's judgments on public health protection, with judgments regarding stability of the standard being a legitimate, but secondary consideration. The Administrator's final decision on form is discussed below.

#### d. Administrator's Final Decision Regarding Form

In reaching a final decision on the form of the primary O<sub>3</sub> standard, as described in the proposal and above, the Administrator recognizes that there is not a clear health-based rationale for

selecting a particular nth-highest daily maximum form. Her foremost consideration is the adequacy of the public health protection provided by the combination of all of the elements of the standard, including the form. In this regard, the Administrator recognizes the support from analyses in previous reviews, and from the CASAC in the current review, for the conclusion that the current fourth-high form of the standard, when combined with a revised level as discussed below, provides an appropriate balance between public health protection and a stable target for implementing programs to improve air quality. In particular, she notes that the CASAC concurred that the O<sub>3</sub> 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). Based on these considerations, and on consideration of public comments on form as discussed above, the Administrator judges it appropriate to retain the current fourth-high form (fourth-highest daily maximum 8-hour O<sub>3</sub> concentration, averaged over 3 years) in this final rule.

#### 4. Level

This section summarizes the basis for the Administrator's proposed decision to revise the current standard level (II.C.4.a); discusses public comments, and the EPA's responses, on that proposed decision (II.C.4.b); and presents the Administrator's final decision regarding the level of the primary O<sub>3</sub> standard (II.C.4.c).

##### a. Basis for the Administrator's Proposed Decision on Level

In conjunction with her proposed decisions to retain the current indicator, averaging time, and form (II.C.1 to II.C.3, above), the Administrator proposed to revise the level of the primary O<sub>3</sub> standard to within the range of 65 to 70 ppb. In proposing this range of standard levels, as discussed in section II.E.4 of the proposal, the Administrator carefully considered the scientific evidence assessed in the ISA (U.S. EPA, 2013); 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 (Frey and Samet, 2012; Frey, 2014 a, c); and public input received during the development of these documents.

The Administrator's proposal to revise the standard level built upon her proposed conclusion that the overall body of scientific evidence and exposure/risk information calls into question the adequacy of public health protection afforded by the current primary O<sub>3</sub> standard, particularly for at-risk populations and lifestages. In reaching proposed conclusions on alternative levels for the primary O<sub>3</sub> standard, the Administrator considered 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<sub>3</sub> exposures.

As was the case for her consideration of the adequacy of the current primary O<sub>3</sub> standard (II.B.3, above), the Administrator placed 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 noted that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following exposures to specific O<sub>3</sub> concentrations. The effects reported in these studies are due solely to O<sub>3</sub> 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 noted 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).

In considering the evidence from controlled human exposure studies, the Administrator first noted that the largest respiratory effects, and the broadest range of effects, have been studied and reported following exposures to 80 ppb O<sub>3</sub> or higher, with most exposure studies conducted at these higher concentrations. Exposures of healthy adults to O<sub>3</sub> 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. The Administrator further noted that O<sub>3</sub> exposure concentrations as low as 72 ppb have been shown to both decrease lung function and increase respiratory

symptoms (Schelegle *et al.*, 2009),<sup>121</sup> a combination that meets the ATS criteria for an adverse response, and that exposures as low as 60 ppb have been reported to decrease lung function and increase airway inflammation.

Based on this evidence, the Administrator reached the initial conclusion that the results of controlled human exposure studies strongly support setting the level of a revised O<sub>3</sub> standard no higher than 70 ppb. In reaching this conclusion, she placed a large amount of weight on the importance of setting the level of the standard well below 80 ppb, the exposure concentration at which the broadest range of effects have been studied and reported, and below 72 ppb, the lowest exposure concentration shown to result in the adverse combination of lung function decrements and respiratory symptoms. She placed significant weight on this combination of effects, as did CASAC, in making judgments regarding the potential for adverse responses.

In further considering the potential public health implications of a standard with a level of 70 ppb, the Administrator also considered quantitative estimates of the extent to which such a standard would be expected to limit population exposures to the broader range of O<sub>3</sub> concentrations shown in controlled human exposure studies to cause respiratory effects. In doing so, she focused on estimates of O<sub>3</sub> exposures of concern at or above the benchmark concentrations of 60, 70, and 80 ppb. The Administrator judged that the evidence supporting the occurrence of adverse respiratory effects is strongest for exposures at or above the 70 and 80 ppb benchmarks. Therefore, she placed a large amount of emphasis on the importance of setting a standard that limits exposures of concern at or above these benchmarks.

The Administrator expressed less confidence that adverse effects will occur following exposures to O<sub>3</sub> concentrations as low as 60 ppb. In reaching this conclusion, she highlighted the fact that statistically significant increases in respiratory symptoms, combined with lung function decrements, have not been reported following exposures to 60 or 63 ppb O<sub>3</sub>, though several studies have evaluated the potential for such effects (Kim *et al.*, 2011; Schelegle *et al.*, 2009;

Adams, 2006).<sup>122</sup> The proposal specifically stated that “[t]he Administrator has decreasing confidence that adverse effects will occur following exposures to O<sub>3</sub> concentrations below 72 ppb. In particular, compared to O<sub>3</sub> exposure concentrations at or above 72 ppb, she has less confidence that adverse effects will occur following exposures to O<sub>3</sub> concentrations as low as 60 ppb” (79 FR 73304–05).

However, she noted the possibility for adverse effects following such exposures given that: (1) CASAC judged the adverse combination of lung function decrements and respiratory symptoms “almost certainly occur in some people” following exposures to O<sub>3</sub> concentrations below 72 ppb (though CASAC did not specify or otherwise indicate how far below) (Frey, 2014c, p. 6); (2) CASAC indicated the moderate lung function decrements (*i.e.*, FEV<sub>1</sub> decrements  $\geq 10\%$ ) that occur in some healthy adults following exposures to 60 ppb O<sub>3</sub> could be adverse to people with lung disease; and (3) airway inflammation has been reported following exposures as low as 60 ppb O<sub>3</sub>. She also took note of CASAC advice that the occurrence of exposures of concern at or above 60 ppb is an appropriate consideration for people with asthma (Frey, 2014c, p. 6). Therefore, while the Administrator expressed less confidence that adverse effects will occur following exposures to O<sub>3</sub> concentrations as low as 60 ppb, compared to 70 ppb and above, based on the evidence and CASAC advice she also gave some consideration to exposures of concern for the 60 ppb benchmark.

Due to interindividual variability in responsiveness, the Administrator further noted that not every occurrence of an exposure of concern will result in an adverse effect, and that repeated occurrences of some of the effects demonstrated following exposures of concern could increase the likelihood of adversity (U.S. EPA, 2013, section 6.2.3). Therefore, the Administrator was most concerned about protecting at-risk populations against repeated occurrences of exposures of concern. Based on the above considerations, the Administrator focused on the extent to which a revised standard with a level of 70 ppb would be expected to protect populations from experiencing two or more O<sub>3</sub> exposures of concern (*i.e.*, as a surrogate for repeated exposures).

As illustrated in Table 1 in the proposal (and Table 1 above), the Administrator noted that, in urban study areas, a revised standard with a level of 70 ppb is estimated to eliminate the occurrence of two or more exposures of concern to O<sub>3</sub> concentrations at and above 80 ppb and to virtually eliminate the occurrence of two or more exposures of concern to O<sub>3</sub> concentrations at and above 70 ppb, even in the worst-case urban study area and year evaluated. Though the Administrator acknowledged greater uncertainty with regard to the occurrence of adverse effects following exposures to 60 ppb, she noted 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 than 99% of children in individual urban study areas) from experiencing two or more exposures of concern at or above the 60 ppb benchmark. Compared to the current standard, this represents a reduction of more than 60%.<sup>123</sup>

In further evaluating the potential public health impacts of a standard with a level of 70 ppb, the Administrator also considered the HREA estimates of O<sub>3</sub>-induced lung function decrements. To inform her consideration of these decrements, the Administrator took note of CASAC advice that “estimation of FEV<sub>1</sub> decrements of  $\geq 15\%$  is appropriate as a scientifically relevant surrogate for adverse health outcomes in active healthy adults, whereas an FEV<sub>1</sub> decrement of  $\geq 10\%$  is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease” (Frey, 2014c, p. 3).

Although these FEV<sub>1</sub> decrements provide perspective on the potential for the occurrence of adverse respiratory effects following O<sub>3</sub> exposures, the Administrator agreed 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 judged that not every estimated occurrence of an O<sub>3</sub>-induced FEV<sub>1</sub> decrement will be adverse and

<sup>123</sup> The Administrator judged that the evidence is less compelling, and indicates greater uncertainty, with regard to the potential for adverse effects following single occurrences of O<sub>3</sub> exposures of concern. While acknowledging this greater uncertainty, she noted that a standard with a level of 70 ppb would also be expected to virtually eliminate all occurrences (including single occurrences) of exposures of concern at or above 80 ppb, even in the worst-case year and location. She also judged that such a standard will 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.

<sup>121</sup> As noted above, for the 70 ppb target exposure concentration, Schelegle *et al.* (2009) reported that the actual mean exposure concentration was 72 ppb.

<sup>122</sup> In the study by Schelegle, for the 60 ppb target exposure concentration, study authors reported that the actual mean exposure concentration was 63 ppb.



that repeated occurrences of moderate responses could lead to more serious illness. Therefore, the Administrator noted increasing concern about the potential for adversity as the number of occurrences increases and, as a result, she focused primarily on estimates of two or more O<sub>3</sub>-induced FEV<sub>1</sub> decrements (*i.e.*, as a surrogate for repeated exposures).<sup>124</sup>

The Administrator noted that a revised O<sub>3</sub> 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<sub>3</sub>-induced FEV<sub>1</sub> decrements  $\geq 15\%$ , and about 89 to 94% from experiencing two or more decrements  $\geq 10\%$ . She judged that these estimates reflect important risk reductions, compared to the current standard. Given these estimates, as well as estimates of one or more decrements per season (about which she was less concerned (79 FR 75290, December 17, 2014)), the Administrator concluded that a revised standard with a level of 70 ppb would be expected to provide substantial protection against the risk of O<sub>3</sub>-induced lung function decrements, and would be expected to result in important reductions in such risks, compared to the current standard. The Administrator further noted, however, that 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, in the proposal the Administrator viewed lung function risk estimates as providing a more limited basis than exposures of concern for distinguishing between the degrees of public health protection provided by alternative standard levels (79 FR 75306 n. 164).

In next considering the additional protection that would be expected from standard levels below 70 ppb, the Administrator evaluated the extent to which a standard with a level of 65 ppb would be expected to further limit O<sub>3</sub> exposures of concern and O<sub>3</sub>-induced lung function decrements. In addition to eliminating almost all exposures of concern to O<sub>3</sub> concentrations at or above 80 and 70 ppb, even in the worst-case years and locations, the Administrator noted that a revised standard with a

level of 65 ppb would be expected to protect more than 99% of children in urban study areas from experiencing two or more exposures of concern at or above 60 ppb and to substantially reduce the occurrence of one or more such exposures, compared to the current standard. With regard to O<sub>3</sub>-induced lung function decrements, an O<sub>3</sub> 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<sub>3</sub>-induced FEV<sub>1</sub> decrements  $\geq 15\%$  and about 91 to 99% from experiencing two or more decrements  $\geq 10\%$ .<sup>125</sup>

Taken together, the Administrator concluded that the evidence from controlled human exposure studies, and the information from quantitative analyses that draw upon these studies, provide strong support for standard levels from 65 to 70 ppb. In particular, she based this conclusion on the fact that such standard levels would be well below the O<sub>3</sub> exposure concentration shown to result in the widest range of respiratory effects (*i.e.*, 80 ppb),<sup>126</sup> and below the lowest O<sub>3</sub> 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<sub>3</sub> exposures of concern for all of the benchmarks evaluated (*i.e.*, 60, 70, and 80 ppb) and in the risk of O<sub>3</sub>-induced lung function decrements  $\geq 10$  and 15%.

In further considering the evidence and exposure/risk information, the Administrator considered the extent to which the epidemiologic evidence also provides support for standard levels from 65 to 70 ppb. In particular, the Administrator noted 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 distributions of short-term ambient O<sub>3</sub> concentrations below those present in the locations of all the single-city epidemiologic studies of hospital admissions or emergency department visits analyzed. She concluded 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.<sup>127</sup>

The Administrator noted additional uncertainty in interpreting air quality in locations of multicity epidemiologic studies of short-term O<sub>3</sub> for the purpose of evaluating alternative standard levels (II.D.1 and U.S. EPA, 2014c, section 4.4.1). While acknowledging this uncertainty, and therefore placing less emphasis on these analyses of study location air quality, she noted that PA analyses suggest that standard levels of 65 or 70 ppb would require reductions, beyond those required by the current standard, in ambient O<sub>3</sub> concentrations present in several of the locations that provided the basis for statistically significant O<sub>3</sub> health effect associations in multicity studies.

In further evaluating information from epidemiologic studies, the Administrator considered the HREA's epidemiology-based risk estimates for O<sub>3</sub>-associated morbidity or mortality (U.S. EPA, 2014a, Chapter 7). 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 placed relatively less weight on epidemiology-based risk estimates. In doing so, she noted 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.

In considering epidemiology-based risk estimates, the Administrator focused on risks associated with O<sub>3</sub> concentrations in the upper portions of ambient distributions, given the greater uncertainty associated with the shapes of concentration-response curves for O<sub>3</sub> concentrations in the lower portions of ambient distributions (*i.e.*, below about 20 to 40 ppb depending on the O<sub>3</sub> metric, health endpoint, and study population) (U.S. EPA, 2013, section 2.5.4.4). The Administrator further noted that experimental studies provide the strongest evidence for O<sub>3</sub>-induced effects following exposures to O<sub>3</sub> concentrations corresponding to the upper portions of typical ambient

<sup>124</sup> In the proposal, the Administrator further judged that it would not be appropriate to set a standard that is intended to eliminate all O<sub>3</sub>-induced FEV<sub>1</sub> decrements. She noted that this is consistent with CASAC advice, which did not include a recommendation to set the standard level low enough to eliminate all O<sub>3</sub>-induced FEV<sub>1</sub> decrements  $\geq 10$  or 15% (Frey, 2014c).

<sup>125</sup> Although the Administrator was less concerned about the public health implications of single O<sub>3</sub>-induced lung function decrements, she also noted that a revised standard with a level of 65 ppb is estimated to reduce the risk of one or more O<sub>3</sub>-induced decrements per season, compared to the current standard.

<sup>126</sup> Although the widest range of effects have been evaluated following exposures to 80 ppb O<sub>3</sub>, there is no evidence that 80 ppb is a threshold for these effects.

<sup>127</sup> The Administrator also concluded that analyses in the HREA and PA indicate that a standard with an 8-hour averaging time, coupled with the current fourth-high form and a level from 65 to 70 ppb, would be expected to provide increased protection, compared to the current standard, against the long-term O<sub>3</sub> concentrations that have been reported to be associated with respiratory morbidity or mortality (79 FR 75293; 75308).



distributions. In particular, as discussed above, she noted controlled human exposure studies showing respiratory effects following exposures to O<sub>3</sub> concentrations at or above 60 ppb (79 FR 75308, December 17, 2014).

Therefore, in considering risks associated with O<sub>3</sub> concentrations in the upper portions of ambient distributions, the Administrator focused on the extent to which revised standards with levels of 70 or 65 ppb are estimated to reduce the risk of premature deaths associated with area-wide O<sub>3</sub> concentrations at or above 40 ppb and 60 ppb.

Given all of the above evidence, exposure/risk information, and advice from CASAC, the Administrator proposed to revise the level of the current primary O<sub>3</sub> standard to within the range of 65 to 70 ppb. In considering CASAC advice on the range of standard levels, the Administrator placed a large amount of weight on 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. She also noted that although CASAC expressed concern about the margin of safety at a level of 70 ppb, it further acknowledged that the choice of a level within the range recommended based on scientific evidence is a policy judgment (Frey, 2014c, p. ii). While she agreed 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 concluded 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.

In considering the appropriateness of standard levels below 65 ppb, the Administrator noted 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 making the decision to not propose levels below 65 ppb, she focused on CASAC's rationale for a level of 60 ppb, which focused on the importance of limiting exposures to O<sub>3</sub> concentrations as low as 60 ppb (Frey, 2014c, p. 7). As discussed above, the Administrator agreed that it is appropriate to consider the implications of a revised standard level for estimated exposures of concern at or above 60 ppb. She noted 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<sub>3</sub> concentrations at or above 60 ppb, particularly the occurrence of two or

more exposures. When she further considered 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 judged that alternative standard levels below 65 ppb are not needed to further reduce such exposures.

#### b. Comments on Level

A number of groups representing medical, public health, or environmental organizations; some state agencies; and many individuals submitted comments on the appropriate level of a revised primary O<sub>3</sub> standard.<sup>128</sup> Virtually all of these commenters supported setting the standard level within the range recommended by CASAC (*i.e.*, 60 to 70). Some expressed support for the overall CASAC range, without specifying a particular level within that range, while others expressed a preference for the lower part of the CASAC range, often emphasizing support for a level of 60 ppb. Some of these commenters stated that if the EPA does not set the level at 60 ppb, then the level should be set no higher than 65 ppb (*i.e.*, the lower bound of the proposed range of standard levels).

To support their views on the level of a revised standard, some commenters focused on overarching issues related to the statutory requirements for the NAAQS. For example, some commenters maintained that the primary NAAQS must be set at a level at which there is an absence of adverse effects in sensitive populations. While this argument has some support in the case law and in the legislative history to the 1970 CAA (see *Lead Industries Ass'n v. EPA*, 647 F. 2d 1147, 1153 (D.C. Cir. 1980)), it is well established that the NAAQS are not meant to be zero risk standards. See *Lead Industries v. EPA*, 647 F.2d at 1156 n.51; *Mississippi v. EPA*, 744 F. 3d at 1351. From the inception of the NAAQS standard-setting process, the EPA and the courts have acknowledged that scientific uncertainties in general, and the lack of clear thresholds in pollutant effects in particular, preclude any such definitive determinations. *Lead Industries*, 647 F. 2d at 1156 (setting standard at a level which would remove most but not all

sub-clinical effects). Likewise, the House report to the 1977 amendments addresses this question (H. Rep. 95–294, 95th Cong. 1st sess. 127):<sup>129</sup>

Some have suggested that since the standards are to protect against all known or anticipated effects and since no safe threshold can be established, the ambient standards should be set at zero or background levels. Obviously, this no-risk philosophy ignores all economic and social consequences and is impractical. This is particularly true in light of the legal requirement for mandatory attainment of the national primary standards within 3 years.

Thus, post-1970 jurisprudence makes clear the impossibility, and lack of legal necessity, for NAAQS removing all health risk. See *ATA III*, 283 F. 3d at 360 (“[t]he lack of a threshold concentration below which these pollutants are known to be harmless makes the task of setting primary NAAQS difficult, as EPA must select standard levels that reduce risks sufficiently to protect public health even while recognizing that a zero-risk standard is not possible”); *Mississippi*, 744 F. 3d at 1351 (same); see also *id.* at 1343 (“[d]etermining what is ‘requisite’ to protect the ‘public health’ with an ‘adequate’ margin of safety may indeed require a contextual assessment of acceptable risk. See *Whitman*, 531 U.S. at 494–95 (Breyer J. concurring)”).

In this review, EPA is setting a standard based on a careful weighing of available evidence, including a weighing of the strengths and limitations of the evidence and underlying scientific uncertainties therein. The Administrator's choice of standard level is rooted in her evaluation of the evidence, which reflects her legitimate uncertainty as to the O<sub>3</sub> concentrations at which the public would experience adverse health effects. This is a legitimate, and well recognized, exercise of “reasoned decision-making.” *ATA III*, 283 F. 3d at 370; see also *id.* at 370 (“EPA's inability to guarantee the accuracy or increase the precision of the . . . NAAQS in no way undermines the standards' validity. Rather, these limitations indicate only that significant scientific uncertainty remains about the health effects of fine particulate matter at low atmospheric concentration. . . .”); *Mississippi*, 744 F. 3d at 1352–53 (appropriate for EPA to balance scientific uncertainties in determining level of revised O<sub>3</sub> NAAQS).

<sup>128</sup> In general, commenters who expressed the view that the EPA should retain the current O<sub>3</sub> NAAQS (*i.e.*, commenters representing industry and business groups, and some states) did not provide comments on alternative standard levels. As a result, this section focuses primarily on comments from commenters who expressed support for the proposed decision to revise the current primary O<sub>3</sub> standard.

<sup>129</sup> Similarly, Senator Muskie remarked during the floor debates on the 1977 Amendments that “there is no such thing as a threshold for health effects. Even at the national primary standard level, which is the health standard, there are health effects that are not protected against”. 123 Cong. Rec. S9423 (daily ed. June 10, 1977).

In an additional overarching comment, some commenters also fundamentally objected to the EPA's consideration of exposure estimates in reaching conclusions on the primary O<sub>3</sub> standard. These commenters' general assertion was that NAAQS must be established so as to be protective, with an adequate margin of safety, regardless of the activity patterns that feed into exposure estimates. They contended that "[a]ir quality standards cannot rely on avoidance behavior in order to protect the public health and sensitive groups" and that "[i]t would be unlawful for EPA to set the standard at a level that is contingent upon people spending most of their time indoors" (e.g., ALA *et al.*, p. 124). To support these comments, for example, ALA *et al.* analyzed ambient monitoring data from Core-Based Statistical Areas (CBSAs) with design values between 66–70 ppb (Table 17, pp. 145–151 in ALA *et al.*) and 62–65 ppb (Table 18, pp. 153–154 in ALA *et al.*) and pointed out that there are many more days with ambient concentrations above the benchmark levels than were estimated in the EPA's exposure analysis (*i.e.*, at and above the benchmark level of 60, 70 and 80 ppb).

The EPA disagrees with these commenters' conclusions regarding the appropriateness of considering exposure estimates, and notes that NAAQS must be "requisite" (*i.e.*, "sufficient, but not more than necessary" (*Whitman*, 531 U.S. at 473)) to protect the "public health" ("the health of the public" (*Whitman*, 531 U.S. at 465)). Estimating exposure patterns based on extensive available data<sup>130</sup> is a reasonable means of ascertaining that standards are neither under- nor over-protective, and that standards address issues of public health rather than health issues pertaining only to isolated individuals.<sup>131</sup> Behavior patterns are critical in assessing whether ambient concentrations of O<sub>3</sub> may pose a public health risk.<sup>132</sup> Exposures to ambient or near-ambient O<sub>3</sub> concentrations have only been shown to result in potentially

adverse effects if the ventilation rates of people in the exposed populations are raised to a sufficient degree (e.g., through physical exertion) (U.S. EPA, 2013, section 6.2.1.1).<sup>133</sup> Ignoring whether such elevated ventilation rates are actually occurring, as advocated by these commenters, would not provide an accurate assessment of whether the public health is at risk. Indeed, a standard established without regard to behavior of the public would likely lead to a standard which is more stringent than necessary to protect the public health.

While setting the primary O<sub>3</sub> standard based only on ambient concentrations, without consideration of activity patterns and ventilation rates, would likely result in a standard that is over-protective, the EPA also concludes that setting a standard based on the assumption that people will adjust their activities to avoid exposures on high-pollution days would likely result in a standard that is under-protective. The HREA's exposure assessment does not make this latter assumption.<sup>134</sup> The time-location-activity diaries that provided the basis for exposure estimates reflect actual variability in human activities. While some diary days may reflect individuals spending less time outdoors than would be typical for them, it is similarly likely that some days reflect individuals spending more time outdoors than would be typical. Considering the actual variability in time-location-activity patterns is at the least a permissible way of identifying standards that are neither over- nor under-protective.<sup>135</sup>

Further, the EPA sees nothing in the CAA that prohibits consideration of the O<sub>3</sub> exposures that could result in effects of public health concern. While a number of judicial opinions have upheld the EPA's decisions in other NAAQS reviews to place little weight on particular risk or exposure analyses (*i.e.*, because of scientific uncertainties

in those analyses), none of these opinions have suggested that such analyses are irrelevant because actual exposure patterns do not matter. See, e.g. *Mississippi*, 744 F. 3d at 1352–53; *ATA III*, 283 F. 3d at 373–74. Therefore, because behavior patterns are critical in assessing whether ambient concentrations of O<sub>3</sub> may pose a public health risk, the EPA disagrees with the views expressed by these commenters objecting to the consideration of O<sub>3</sub> exposures in reaching decisions on the primary O<sub>3</sub> standard.

In addition to these overarching comments, a number of commenters supported their views on standard level by highlighting specific aspects of the scientific evidence, exposure/risk information, and/or CASAC advice. Key themes expressed by these commenters included the following: (1) Controlled human exposure studies provide strong evidence of adverse lung function decrements and airway inflammation in healthy adults following exposures to O<sub>3</sub> concentrations as low as 60 ppb, and at-risk populations would be likely to experience more serious effects or effects at even lower concentrations; (2) epidemiologic studies provide strong evidence for associations with mortality and morbidity in locations with ambient O<sub>3</sub> concentrations below 70 ppb, and in many cases in locations with concentrations near and below 60 ppb; (3) quantitative analyses in the HREA are biased such that they understate O<sub>3</sub> exposures and risks, and the EPA's interpretation of lung function risk estimates is not appropriate and not consistent with other NAAQS; and (4) the EPA must give deference to CASAC advice, particularly CASAC's policy advice to set the standard level below 70 ppb. The next sections discuss comments related to each of these points, and provide the EPA's responses to those comments. More detailed discussion of individual comments, and the EPA's responses, is provided in the Response to Comments document.

#### i. Effects in Controlled Human Exposure Studies

Some commenters who advocated for a level of 60 ppb (or absent that, for 65 ppb) asserted that controlled human exposure studies have reported adverse respiratory effects in healthy adults following exposures to O<sub>3</sub> concentrations as low as 60 ppb. These commenters generally based their conclusions on the demonstration of FEV<sub>1</sub> decrements ≥ 10% and increased airway inflammation following exposures of healthy adults to 60 ppb O<sub>3</sub>. They concluded that even more serious effects would occur in at-risk

<sup>130</sup> The CHAD database used in the HREA's exposure assessment contains over 53,000 individual daily diaries including time-location-activity patterns for individuals of both sexes across a wide range of ages (U.S. EPA, 2014a, Chapter 5).

<sup>131</sup> CASAC generally agreed with the EPA's methodology for characterizing exposures of concern (Frey, 2014a, pp. 5–6).

<sup>132</sup> See 79 FR 75269 ("The activity pattern of individuals is an important determinant of their exposure. Variation in O<sub>3</sub> 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<sub>3</sub>. Activity patterns vary both among and within individuals, resulting in corresponding variations in exposure across a population and over time" (internal citations omitted).

<sup>133</sup> For healthy young adults exposed at rest for 2 hours, 500 ppb is the lowest O<sub>3</sub> concentration reported to produce a statistically significant O<sub>3</sub>-induced group mean FEV<sub>1</sub> decrement (U.S. EPA, 2013, section 6.2.1.1).

<sup>134</sup> The EPA was aware of the possibility of averting behavior during the development of the HREA, and that document includes sensitivity analyses to provide perspective on the potential role of averting behavior in modifying O<sub>3</sub> exposures. As discussed further above (II.B.2.c), these sensitivity analyses were limited and the results were discussed in the proposal within the context of uncertainties in the HREA assessment of exposures of concern.

<sup>135</sup> See *Mississippi*, 744 F. 3d at 1343 ("[d]etermining what is 'requisite' to protect the 'public health' with an 'adequate' margin of safety may indeed require a contextual assessment of acceptable risk. See *Whitman*, 531 U.S. at 494–95 (Breyer, J. concurring . . .)"))

populations exposed to 60 ppb O<sub>3</sub>, and that such populations would experience adverse effects following exposures to O<sub>3</sub> concentrations below 60 ppb.

While the EPA agrees that information from controlled human exposure studies conducted at 60 ppb can help to inform the Administrator's decision on the standard level, the Agency does not agree that this information necessitates a level below 70 ppb. In fact, as discussed in the proposal, a revised O<sub>3</sub> standard with a level of 70 ppb can be expected to provide substantial protection against the effects shown to occur following various O<sub>3</sub> exposure concentrations, including those observed following exposures to 60 ppb. 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 fourth-high form of the O<sub>3</sub> NAAQS, which the Administrator is retaining in the current review (II.C.3), the large majority of days in areas that meet the standard will have 8-hour O<sub>3</sub> concentrations below the level of the standard, with most days well below the level. Therefore, as discussed in the proposal, in considering the degree of protection provided by an O<sub>3</sub> standard with a particular level, it is important to consider the extent to which that standard would be expected to limit population exposures of concern to the broader range of O<sub>3</sub> exposure concentrations shown in controlled human exposure studies to result in health effects. The Administrator's consideration of such exposures of concern is discussed below (II.C.4.c).

Another important part of the Administrator's consideration of exposure estimates is the extent to which she judges that adverse effects could occur following specific O<sub>3</sub> exposures. While controlled human exposure studies provide a high degree of confidence regarding the extent to which specific health effects occur following exposures to O<sub>3</sub> concentrations from 60 to 80 ppb, the Administrator notes that there are no universally accepted criteria by which to judge the adversity of the observed effects. Therefore, in making judgments about the extent to which the effects observed in controlled human exposure studies have the potential to be adverse, the Administrator considers the recommendations of ATS and advice from CASAC (II.A.1.c, above).

As an initial matter, with regard to the effects shown in controlled human exposure studies following O<sub>3</sub> exposures, the Administrator notes the following:

1. The largest respiratory effects, and the broadest range of effects, have been studied and reported following exposures to 80 ppb O<sub>3</sub> or higher, with most exposure studies conducted at these higher concentrations.

Specifically, 6.6-hour exposures of healthy young adults to 80 ppb O<sub>3</sub>, while engaged in quasi-continuous, moderate exertion, can decrease lung function, increase airway inflammation, increase respiratory symptoms, result in airway hyperresponsiveness, and decrease lung host defenses.

2. Exposures of healthy young adults for 6.6 hours to O<sub>3</sub> concentrations as low as 72 ppb, while engaged in quasi-continuous, moderate exertion, have been shown to both decrease lung function and result in respiratory symptoms.

3. Exposures of healthy young adults for 6.6 hours to O<sub>3</sub> concentrations as low as 60 ppb, while engaged in quasi-continuous, moderate exertion, have been shown to decrease lung function and to increase airway inflammation.

To inform her judgments on the potential adversity to public health of these effects reported in controlled human exposure studies, as in the proposal, the Administrator considers the ATS recommendation that "reversible loss of lung function in combination with the presence of symptoms should be considered adverse" (ATS, 2000a). She notes that this combination of effects has been shown to occur following 6.6-hour exposures to O<sub>3</sub> concentrations at or above 72 ppb. In considering these effects, CASAC observed that "the combination of decrements in FEV<sub>1</sub> 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).

Regarding the potential for adverse effects following exposures to lower concentrations, 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 O<sub>3</sub> concentrations below 72 ppb (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<sub>3</sub> 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 [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 (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.

The Administrator notes that while adverse effects could occur following exposures at least somewhat below 72 ppb, the combination of statistically significant increases in respiratory symptoms and decrements in lung function has not been reported following 6.6-hour exposures to average O<sub>3</sub> concentrations of 60 ppb or 63 ppb, though studies have evaluated the potential for such effects (Adams, 2006; Schelegle *et al.*, 2009; Kim *et al.*, 2011). In the absence of this combination, the Administrator looks to additional ATS recommendations and CASAC advice in order to inform her judgments regarding the potential adversity of the effects that have been observed following O<sub>3</sub> exposures as low as 60 ppb.

With regard to ATS, she first notes the recommendations that "a small, transient loss of lung function, by itself, should not automatically be designated as adverse" and that "[f]ew . . . biomarkers have been validated sufficiently that their responses can be used with confidence to define the point at which a response should be equated to an adverse effect warranting preventive measures" (ATS, 2000a).<sup>136</sup> Based on these recommendations, compared to effects following exposures at or above 72 ppb, the Administrator has less confidence in the adversity of the respiratory effects that have been observed following exposures to 60 or 63 ppb.

She further notes that some commenters who advocated for a level of 60 ppb also focused on ATS recommendations regarding population-level risks. These commenters specifically stated that lung function decrements "may be adverse in terms of 'population risk,' where exposure to air pollution increases the risk to the population even though it might not harm lung function to a degree that is, on its own, 'clinically important' to an individual" (*e.g.*, ALA *et al.*, p. 118). These commenters asserted that the EPA

<sup>136</sup> With regard to this latter recommendation, as discussed above (II.A.1.c), the ATS concluded that elevations of biomarkers such as cell numbers and 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.

has not appropriately considered the potential for such population-level risk. Contrary to the views expressed by these commenters, the Administrator carefully considers the potential for population risk, particularly within the context of the ATS recommendation that “a shift in the risk factor distribution, and hence the risk profile of the exposed population, should be considered adverse, even in the absence of the immediate occurrence of frank illness” (ATS, 2000a). Given that exposures to 60 ppb O<sub>3</sub> have been shown in controlled human exposure studies to cause transient and reversible decreases in group mean lung function, the Administrator notes the potential for such exposures to result in similarly transient and reversible shifts in the risk profile of an exposed population. However, in contrast to commenters who advocated for a level of 60 ppb, the Administrator also notes that the available evidence does not provide information on the extent to which a short-term, transient decrease in lung function in a population, as opposed to a longer-term or permanent decrease, could affect the risk of other, more serious respiratory effects (*i.e.*, change the risk profile of the population). This uncertainty, together with the additional ATS recommendations noted above, indicates to the Administrator that her judgment that there is uncertainty in the adversity of the effects shown to occur at 60 ppb is consistent with ATS recommendations.<sup>137</sup>

With regard to CASAC advice, the Administrator notes that, while CASAC clearly advised the EPA to consider the health effects shown to occur following exposures to 60 ppb O<sub>3</sub>, its advice regarding the adversity of those effects is less clear. In particular, she notes that CASAC was conditional about whether the lung function decrements observed in some people at 60 ppb (*i.e.*, FEV<sub>1</sub> decrements  $\geq$  10%) are adverse. Specifically, CASAC stated that these decrements “could be adverse in individuals with lung disease” (Frey, 2014c, p. 7, *emphasis added*) and that they provide a “surrogate for adverse health outcomes for people with asthma and lung disease” (Frey, 2014c, p. 3, *emphasis added*). Further, CASAC did not recommend considering standard levels low enough to eliminate O<sub>3</sub>-induced FEV<sub>1</sub> decrements  $\geq$  10% (Frey,

2014c). With regard to the full range of effects shown to occur at 60 ppb (*i.e.*, FEV<sub>1</sub> decrements, airway inflammation), CASAC stated that exposures of concern for the 60 ppb benchmark are “*relevant for consideration*” with respect to people with asthma (Frey, 2014c, p. 6, *italics added*). In addition, “[t]he CASAC concurs with EPA staff regarding the finding based on scientific evidence 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, *italics added*). The Administrator contrasts these statements with CASAC’s clear advice that “the combination of decrements in FEV<sub>1</sub> 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).

Based on her consideration of all of the above recommendations and advice noted above, the Administrator judges that, compared to exposure concentrations at and above 72 ppb, there is greater uncertainty with regard to the adversity of effects shown to occur following O<sub>3</sub> exposures as low as 60 ppb. However, based on the effects that have been shown to occur at 60 ppb (*i.e.*, lung function decrements, airway inflammation), and CASAC advice indicating the importance of considering these effects (though its advice regarding the adversity of effects at 60 ppb is less clear), she concludes that it is appropriate to give some consideration to the extent to which a revised standard could allow such effects.

In considering estimates of exposures of concern for the 60, 70, and 80 ppb benchmarks within the context of her judgments on adversity, the Administrator notes that, due to interindividual variability in responsiveness, not every occurrence of an exposure of concern will result in an adverse effect. As discussed above (II.B.2.b.i), this point was highlighted by some commenters who opposed revision of the current standard, based on their analysis of effects shown to occur following exposures to 72 ppb O<sub>3</sub>. This point was also highlighted by some commenters who advocated for a level of 60 ppb, based on the discussion of O<sub>3</sub>-induced inflammation in the proposal. In particular, this latter group of commenters highlighted discussion from the proposal indicating that “[i]nflammation induced by a single O<sub>3</sub>

exposure can resolve entirely but, as noted in the ISA (U.S. EPA, 2013, p. 6–76), ‘continued acute inflammation can evolve into a chronic inflammatory state’” (*e.g.*, ALA *et al.*, p. 48). Consistent with these comments, and with her consideration of estimated exposures of concern in the proposal, the Administrator judges that the types of respiratory effects that can occur following exposures of concern, particularly if experienced repeatedly, provide a plausible mode of action by which O<sub>3</sub> may cause other more serious effects. Because of this, as in the proposal, the Administrator is most concerned about protecting against repeated occurrences of exposures of concern.

The Administrator’s consideration of estimated exposures of concern is discussed in more detail below (II.C.4.b.iv, II.C.4.c). In summary, contrary to the conclusions of commenters who advocated for a level of 60 ppb, the Administrator judges that a revised standard with a level of 70 ppb will effectively limit the occurrence of the O<sub>3</sub> exposures for which she is most confident in the adversity of the resulting effects (*i.e.*, based on estimates for the 70 and 80 ppb benchmarks). She further concludes that such a standard will provide substantial protection against the occurrence of O<sub>3</sub> exposures for which there is greater uncertainty in the adversity of effects (*i.e.*, based on estimates for the 60 ppb benchmark).

As noted above, commenters also pointed out that benchmark concentrations are based on studies conducted in healthy adults, whereas at-risk populations are likely to experience more serious effects and effects at lower O<sub>3</sub> exposure concentrations. In considering this issue, the EPA notes CASAC’s endorsement of 60 ppb as the lower end of the range of benchmarks for evaluation, and its advice that “the 60 ppb-8hr exposure benchmark is relevant for consideration with respect to adverse effects on asthmatics” (Frey, 2014c, p. 6). As discussed in detail below (II.C.4.c), the Administrator has carefully considered estimated exposures of concern for the 60 ppb benchmark. In addition, though the available information does not support the identification of specific benchmarks below 60 ppb that could be appropriate for consideration for at-risk populations, and though CASAC did not recommend consideration of any such benchmarks, the EPA expects that a revised standard with a level of 70 ppb will also reduce the occurrence of exposures to O<sub>3</sub> concentrations at least somewhat below 60 ppb (U.S. EPA,

<sup>137</sup> ATS provided additional recommendations to help inform judgments regarding the adversity of air pollution-related effects (*e.g.*, related to “quality of life”), though it is not clear whether, or how, such recommendations should be applied to the respiratory effects observed in controlled human exposure studies following 6.6-hour O<sub>3</sub> exposures (ATS, 200a, p. 672).

2014a, Figures 4–9 and 4–10).<sup>138</sup> Thus, even if some members of at-risk populations may experience effects following exposures to O<sub>3</sub> concentrations somewhat below 60 ppb, a revised level of 70 ppb would be expected to reduce the occurrence of such exposures.<sup>139</sup> Therefore, the EPA has considered O<sub>3</sub> exposures that could be relevant for at-risk populations such as children and people with asthma, and does not agree that controlled human exposure studies reporting respiratory effects in healthy adults following exposures to 60 ppb O<sub>3</sub> necessitate a standard level below 70 ppb.

#### ii. Epidemiologic Studies

Commenters representing environmental and public health organizations also highlighted epidemiologic studies that, in their view, provide strong evidence for associations with mortality and morbidity in locations with ambient O<sub>3</sub> concentrations near and below 60 ppb. These commenters focused both on the epidemiologic studies evaluated in the PA's analyses of study location air quality (U.S. EPA, 2014c, Chapter 4) and on studies that were not explicitly analyzed in the PA, and in some cases on studies that were not included in the ISA.

The EPA agrees that epidemiologic studies can provide perspective on the degree to which O<sub>3</sub>-associated health effects have been identified in areas with air quality likely to have met various standards. However, as discussed below, we do not agree with the specific conclusions drawn by these commenters regarding the implications of epidemiologic studies for the standard level. As an initial matter in considering epidemiologic studies, the EPA notes its decision, consistent with CASAC advice, to place the most emphasis on information from controlled human exposure studies (II.B.2 and II.B.3, above). This decision reflects the greater certainty in using information from controlled human exposure studies to link specific O<sub>3</sub> exposures with health effects, compared to using air quality information from epidemiologic studies of O<sub>3</sub> for this purpose.

<sup>138</sup> Air quality analyses in the HREA indicate that reducing the level of the primary standard from 75 ppb to 70 ppb will result in reductions in the O<sub>3</sub> concentrations in the upper portions of ambient distributions. This includes 8-hour ambient O<sub>3</sub> concentrations at, and somewhat below, 60 ppb (U.S. EPA, 2014a, Figures 4–9 and 4–10).

<sup>139</sup> The uncertainty associated with the potential adversity of any such effects would be even greater than that discussed above for the 60 ppb benchmark.

While being aware of the uncertainties discussed above (II.B.2.b.ii), in considering what epidemiologic studies can tell us, the EPA notes analyses in the PA (U.S. EPA, 2014c, section 4.4.1) indicating that a revised standard with a level at or below 70 ppb would be expected to maintain distributions of short-term ambient O<sub>3</sub> concentrations below those present in the locations of all of the single-city epidemiologic 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 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 would have met the current standard over the entire study period, but would have violated a standard with a level of 70 ppb.<sup>140</sup> While these analyses provide support for a level at least as low as 70 ppb, the Administrator judges that they do not provide a compelling basis for distinguishing between the appropriateness of 70 ppb and lower standard levels.

As in the proposal, the EPA acknowledges additional uncertainty in interpreting air quality in locations of multicity epidemiologic studies of short-term O<sub>3</sub> for the purpose of evaluating alternative standard levels (U.S. EPA, 2014c, sections 3.1.4.2, 4.4.1). In particular, the PA concludes that interpretation of such air quality information is complicated by uncertainties in the extent to which multicity effect estimates (*i.e.*, which are based on combining estimates from multiple study locations) can be attributed to ambient O<sub>3</sub> in the subset of study locations that would have met a particular standard, versus O<sub>3</sub> in the study locations that would have violated the standard. While giving only limited weight to air quality analyses in these study areas because of this uncertainty, the EPA also notes PA analyses indicating that a standard level at or below 70 ppb would require additional reductions, beyond those required by the current standard, in the ambient O<sub>3</sub> concentrations that provided the basis for statistically significant O<sub>3</sub> health effect associations in multicity epidemiologic studies. As

<sup>140</sup> As noted above (II.B.2.b.ii and II.B.3), the studies by Silverman and Ito (2010) and Strickland *et al.* (2010) provided support for the Administrator's decision to revise the current primary O<sub>3</sub> standard, but do not provide insight into the appropriateness of specific standard levels below 75 ppb.

was the case for the single-city studies, and contrary to the views expressed by the commenters noted above, the Administrator judges that these studies do not provide a compelling basis for distinguishing between the appropriateness of alternative standard levels at or below 70 ppb.

In some cases, commenters highlighted studies that were assessed in the 2008 review of the O<sub>3</sub> NAAQS, but were not included in the ISA in the current review. These commenters asserted that such studies support the occurrence of O<sub>3</sub> health effect associations in locations with air quality near or, in some cases, below 60 ppb. Specifically, commenters highlighted a number of studies included in the 2007 Staff Paper that were not included in the ISA, claiming that these studies support a standard level below 70 ppb, and as low as 60 ppb.

As an initial matter with regard to these studies, the EPA notes that the focus of the ISA is on assessing the most policy-relevant scientific evidence. In the current review, the ISA considered over 1,000 new studies that have been published since the last review. Thus, it is not surprising that, as the body of evidence has been strengthened since the last review, some of the studies considered in the last review are no longer among the most policy relevant. However, based on the information included in the 2007 Staff Paper, the EPA does not agree that the studies highlighted by commenters provide compelling support for a level below 70 ppb. In fact, as discussed in the Staff Paper in the last review (U.S. EPA, 2007, p. 6–9; Appendix 3B), the O<sub>3</sub> concentrations reported for these studies, and the concentrations highlighted by commenters, were based on averaging across multiple monitors in study areas. Given that the highest monitor in an area is used to determine whether that area meets or violates the NAAQS, the averaged concentrations reported in the Staff Paper are thus not appropriate for direct comparison to the level of the O<sub>3</sub> standard. When the Staff Paper considered the O<sub>3</sub> concentrations measured at individual monitors for the subset of these study areas with particularly low concentrations, they were almost universally found to be above, and in many cases well above, even the current standard level of 75 ppb.<sup>141</sup> Based on the above

<sup>141</sup> For one study conducted in Vancouver, where data from individual monitors did indicate ambient concentrations below the level of the current standard (Vedal *et al.*, 2003), the Staff Paper noted that the study authors questioned whether O<sub>3</sub>, other gaseous pollutants, and PM in this study may be

considerations, and consistent with the Administrator's overall decision to place less emphasis on air quality in locations of epidemiologic studies to select a standard level, the EPA disagrees with commenters who asserted that epidemiologic studies included in the last review, but not cited in the ISA or PA in this review, necessitate a level below 70 ppb. In fact, the EPA notes that these studies are consistent with the majority of the U.S. studies evaluated in the PA in the current review, in that most were conducted in locations that would have violated the current O<sub>3</sub> NAAQS over at least part of the study periods.

### iii. Exposure and Risk Assessments

Some commenters supporting levels below 70 ppb also asserted that quantitative analyses in the HREA are biased such that they understate O<sub>3</sub> exposures of concern and risks of O<sub>3</sub>-induced FEV<sub>1</sub> decrements. Many of these comments are discussed above within the context of the adequacy of the current standard (II.B.2.b.i), including comments pointing out that exposure and risk estimates are based on information from healthy adults rather than at-risk populations; comments noting that the exposure assessment evaluates 8-hour O<sub>3</sub> exposures rather than the 6.6-hour exposures used in controlled human exposure studies; and comments asserting that the EPA's exposure and risk analyses rely on people staying indoors on high pollution days (*i.e.*, averting behavior).

As discussed in section II.B.2.b.i above, while the EPA agrees with certain aspects of these commenters' assertions, we do not agree with their overall conclusions. In particular, there are aspects of the HREA's quantitative analyses that, if viewed in isolation, would tend to either overstate or understate O<sub>3</sub> exposures and/or health risks. While commenters tended to focus on those aspects of the assessments that support their position, they tended to ignore aspects of the assessments that do not support their position (points that were often raised by commenters on the other side of the issue). Rather than viewing the potential implications of these aspects of the HREA assessments in isolation, the EPA considers them together, along with

acting as surrogate markers of pollutant mixes that contain more toxic compounds, "since the low measured concentrations were unlikely, in their opinion, to cause the observed effects" (U.S. EPA, 2007, p. 6–16). The Staff Paper further noted that another study conducted in Vancouver failed to find statistically significant associations with O<sub>3</sub> (Villeneuve *et al.*, 2003).

other issues and uncertainties related to the interpretation of exposure and risk estimates.

For example, some commenters who advocated for a level below 70 ppb asserted that the exposure assessment could underestimate O<sub>3</sub> exposures for highly active populations, including outdoor workers and children who spend a large portion of time outdoors during summer. In support of these assertions, commenters highlighted sensitivity analyses conducted in the HREA. However, as noted in the HREA (U.S. EPA, 2014a, Table 5–10), this aspect of the assessment is likely to have only a "low to moderate" impact on the magnitude of exposure estimates. To put this magnitude in perspective, HREA sensitivity analyses conducted in a single urban study area indicate that, regardless of whether exposure estimates for children are based on all available diaries or on a subset of diaries restricted to simulate highly exposed children, a revised standard with a level of 70 ppb is estimated to protect more than 99% of children from experiencing two or more exposures of concern at or above 70 ppb (U.S. EPA, 2014a, Chapter 5 Appendices, Figure 5G–9).<sup>142</sup> <sup>143</sup> In contrast to the focus of commenters who supported a level below 70 ppb, other aspects of quantitative assessments, some of which were highlighted by commenters who opposed revising the current standard (II.B.2), tend to result in overestimates of O<sub>3</sub> exposures. These aspects are characterized in the HREA as having either a "low," a "low-to-moderate," or a "moderate" impact on the magnitudes of exposure estimates.

In its reviews of the HREA and PA, CASAC recognized many of the uncertainties and issues highlighted by commenters. Even considering these uncertainties, CASAC endorsed the approaches adopted by the EPA to assess O<sub>3</sub> exposures and health risks, and CASAC used exposure and risk estimates as part of the basis for their recommendations on the primary O<sub>3</sub> NAAQS (Frey, 2014c). Thus, as discussed in section II.B.2.b.i above, the

<sup>142</sup> More specifically, based on all children's diaries, just under 0.1% of children are estimated to experience two or more exposures of concern at or above 70 ppb. Based on simulated profiles of highly exposed children, this estimate increased to just over 0.1% (U.S. EPA, 2014a, Chapter 5 Appendices, Figure 5G–9).

<sup>143</sup> In addition, when diaries were selected to mimic exposures that could be experienced by outdoor workers, the percentages of modeled individuals 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 cities and years (*i.e.*, cities and years with the highest exposure estimates) (U.S. EPA, 2014, section 5.4.3.2, Figure 5–14).

EPA disagrees with commenters who claim that the aspects of the quantitative assessments that they highlight lead to overall underestimates of exposures or health risks.<sup>144</sup>

Some commenters further contended that the level of the primary O<sub>3</sub> standard should be set below 70 ppb in order to compensate for the use of a form that allows multiple days with concentrations higher than the standard level. These groups submitted air quality analyses to support their point that the current fourth-high form allows multiple days per year with ambient O<sub>3</sub> concentrations above the level of the standard. While the EPA does not dispute the air quality analyses submitted by these commenters, and agrees that fourth-high form allows multiple days per year with ambient O<sub>3</sub> concentrations above the level of the standard (3 days per year, on average over a 3-year period), the Agency disagrees with commenters' assertion that, because of this, the level of the primary O<sub>3</sub> standard should be set below 70 ppb. As discussed above (II.A.2), the quantitative assessments that informed the Administrator's proposed decision, presented in the HREA and considered in the PA and by CASAC, estimated O<sub>3</sub> exposures and health risks associated with air quality that "just meets" various standards with the current 8-hour averaging time and fourth-high, 3-year average form. Thus, in considering the degree of public health protection appropriate for the primary O<sub>3</sub> standard, the Administrator has considered quantitative exposure and risk estimates that are based a fourth-high form, and therefore on a standard that, as these commenters point out, allows multiple days per year with ambient O<sub>3</sub> concentrations above the level of the standard.

### iv. CASAC Advice

Many commenters, including those representing major medical, public health, or environmental groups; some state agencies; and a large number of individual commenters, focused on CASAC advice in their rationale supporting levels below 70 ppb, and as low as 60 ppb. These commenters generally asserted that the EPA must

<sup>144</sup> As discussed in II.B.2.b above, in weighing the various uncertainties, which can bias exposure results in different directions but tend to have impacts that are similar in magnitude (U.S. EPA, 2014a, Table 5–10), and in light of CASAC's advice based on its review of the HREA and the PA, the EPA continues to conclude that the approach to considering estimated exposures of concern in the HREA, PA, and the proposal reflects an appropriate balance, and provides an appropriate basis for considering the public health protectiveness of the primary O<sub>3</sub> standard.

give deference to CASAC. In some cases, these commenters expressed strong objections to a level of 70 ppb, noting CASAC policy advice that such a level would provide little margin of safety.

The EPA agrees that CASAC advice is an important consideration in reaching a decision on the standard level (see *e.g.* CAA section 307 (d)(3)),<sup>145</sup> though not with commenters' conclusion that CASAC advice necessitates a standard level below 70 ppb. As discussed above (II.C.4.a), the Administrator carefully considered CASAC advice in the proposal, and she judged that her proposed decision to revise the level to within the range of 65 to 70 ppb was consistent with CASAC advice, based on the available science.

As in the proposal, in her final decision on level the Administrator notes CASAC's overall conclusion that "based on the scientific evidence from clinical studies, epidemiologic studies, animal toxicology studies, as summarized in the ISA, the findings from the exposure and risk assessments as summarized in the HREA, and the interpretation of the implications of all of these sources of information as given in the Second Draft PA . . . there is adequate scientific evidence to recommend a range of levels for a revised primary ozone standard from 70 ppb to 60 ppb" (Frey, 2014c, p. 8). Thus, CASAC used the health evidence and exposure/risk information to inform its range of recommended standard levels, a range that included an upper bound of 70 ppb based on the scientific evidence, and it did not use the evidence and information to recommend setting the primary O<sub>3</sub> standard at any specific level within the range of 70 to 60 ppb. In addition, CASAC further stated 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, p. ii).

In addition to its advice based on the scientific evidence, CASAC offered the "policy advice" to set the level below 70 ppb, stating that a standard level of 70 ppb "may not meet the statutory requirement to protect public health with an adequate margin of safety" (Frey, 2014c, p. ii). In supporting its policy advice to set the level below 70 ppb, CASAC noted the respiratory effects that have been shown to occur in controlled human exposure studies following exposures from 60 to 80 ppb

O<sub>3</sub>, and the extent to which various standard levels are estimated to allow the occurrence of population exposures that can result in such effects (Frey, 2014c, pp. 7–8).

The EPA agrees that an important consideration when reaching a decision on level is the extent to which a revised standard is estimated to allow the types of exposures shown in controlled human exposure studies to cause respiratory effects. In reaching her final decision that a level of 70 ppb is requisite to protect public health with an adequate margin of safety (II.C.4.c, below), the Administrator carefully considers the potential for such exposures and effects. In doing so, she emphasizes the importance of setting a standard that limits the occurrence of the exposures about which she is most concerned (*i.e.*, those for which she has the most confidence in the adversity of the resulting effects, which are repeated exposures of concern at or above 70 or 80 ppb, as discussed above in II.C.4.b.i). Based on her consideration of information from controlled human exposure studies in light of CASAC advice and ATS recommendations, the Administrator additionally judges that there is important uncertainty in the extent to which the effects shown to occur following exposures to 60 ppb O<sub>3</sub> are adverse to public health (discussed above, II.C.4.b.i and II.C.4.b.iii). However, based on the effects that have been shown to occur, CASAC advice indicating the importance of considering these effects, and ATS recommendations indicating the potential for adverse population-level effects (II.C.4.b.i, II.C.4.b.iii), she concludes that it is appropriate to give some consideration to the extent to which a revised standard could allow the respiratory effects that have been observed following exposures to 60 ppb O<sub>3</sub>.

When considering the extent to which a revised standard could allow O<sub>3</sub> exposures that have been shown in controlled human exposures studies to result in respiratory effects, the Administrator is most concerned about protecting the public, including at-risk populations, against repeated occurrences of such exposures of concern (II.C.4.b.i, above). In considering the appropriate metric for evaluating repeated occurrences of exposures of concern, the Administrator acknowledges that it is not clear from the evidence, or from the ATS recommendations, CASAC advice, or public comments, how particular numbers of exposures of concern could impact the seriousness of the resulting effects, especially at lower exposure

concentrations. Therefore, the Administrator judges that focusing on HREA estimates of two or more exposures of concern provides a health-protective approach to considering the potential for repeated occurrences of exposures of concern that could result in adverse effects. She notes that other possible metrics for considering repeated occurrences of exposures of concern (*e.g.*, 3 or more, 4 or more, etc.) would result in smaller exposure estimates.

As discussed further below (II.C.4.c), the Administrator notes that a revised standard with a level of 70 ppb is estimated to eliminate the occurrence of two or more exposures of concern to O<sub>3</sub> concentrations at or above 80 ppb and to virtually eliminate the occurrence of two or more exposures of concern to O<sub>3</sub> concentrations at or above 70 ppb (Table 1, above). For the 70 ppb benchmark, this reflects about a 90% reduction in the number of children estimated to experience two or more exposures of concern, compared to the current standard.<sup>146</sup> Even considering the worst-case urban study area and worst-case year evaluated in the HREA, a standard with a level of 70 ppb is estimated to protect more than 99% of children from experiencing two or more exposures of concern to O<sub>3</sub> concentrations at or above 70 ppb (Table 1).

Though the Administrator judges that there is greater uncertainty with regard to the occurrence of adverse effects following exposures as low as 60 ppb, she notes that a revised standard with a level of 70 ppb is estimated to protect the vast majority of children in urban study areas (*i.e.*, about 96% to more than 99% in individual 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 exposures of concern for the 60 ppb benchmark (Table 1). Given the Administrator's uncertainty regarding the adversity of the effects following exposures to 60 ppb O<sub>3</sub>, and her health-protective approach to considering repeated occurrences of exposures of concern, the Administrator judges that this degree of protection is appropriate and that it reflects substantial protection against the occurrence of O<sub>3</sub>-induced effects, including effects for which she judges the adversity to public health is uncertain.

<sup>145</sup> The EPA notes, of course, that the CAA places the responsibility for judging what standard is requisite with the Administrator and only requires that, if her decision differs in important ways from CASAC's advice, she explain her reasoning for differing.

<sup>146</sup> Percent reductions in this section refer to reductions in the number of children in HREA urban study areas (averaged over the years evaluated in the HREA) estimated to experience exposures of concern, based on the information in Table 1 above.



While being less concerned about single occurrences of exposures of concern, especially at lower exposure concentrations, the Administrator also notes that a standard with a level of 70 ppb is estimated to (1) virtually eliminate all occurrences of exposures of concern at or above 80 ppb; (2) protect  $\geq$  about 99% of children in urban study areas from experiencing any exposures of concern at or above 70 ppb; and (3) to achieve substantial reductions (*i.e.*, about 50%), compared to the current standard, in the occurrence of one or more exposures of concern at or above 60 ppb (Table 1).

Given the information and advice noted above (and in II.C.4.b.i, II.C.4.b.iii), the Administrator judges that a revised standard with a level of 70 ppb will effectively limit the occurrence of the O<sub>3</sub> exposures for which she has the most confidence in the adversity of the resulting effects (*i.e.*, based on estimates for the 70 and 80 ppb benchmarks). She further judges that such a standard will provide a large degree of protection against O<sub>3</sub> exposures for which there is greater uncertainty in the adversity of effects (*i.e.*, those observed following exposures to 60 ppb O<sub>3</sub>), contributing to the margin of safety of the standard. See *Mississippi*, 744 F. 3d at 1353 (“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”). Given the considerable protection provided against repeated exposures of concern for all of the benchmarks evaluated, including the 60 ppb benchmark, the Administrator judges that a standard with a level of 70 ppb will provide an adequate margin of safety against the adverse O<sub>3</sub>-induced effects shown to occur following exposures at or above 72 ppb, and judged by CASAC likely to occur following exposures somewhat below 72 ppb.<sup>147</sup>

Contrary to the conclusions of commenters who advocated for a level below 70 ppb, the Administrator notes that her final decision is consistent with CASAC’s advice, based on the scientific evidence, and with CASAC’s focus on

setting a revised standard to further limit the occurrence of the respiratory effects observed in controlled human exposure studies, including effects observed following exposures to 60 ppb O<sub>3</sub>. Given her judgments and conclusions discussed above, and given that the CAA reserves the choice of the standard that is requisite to protect public health with an adequate margin of safety for the judgment of the EPA Administrator, she disagrees with commenters who asserted that CASAC advice necessitates a level below 70 ppb, and as low as 60 ppb. The Administrator’s final conclusions on level are discussed in more detail below (II.C.4.c).

#### c. Administrator’s Final Decision Regarding Level

Having carefully considered the public comments on the appropriate level of the primary O<sub>3</sub> standard, as discussed above and in the Response to Comments document, the Administrator believes her scientific and policy judgments in the proposal remain valid. In conjunction with her decisions to retain the current indicator, averaging time, and form (II.C.1 to II.C.3, above), the Administrator is revising the level of the primary O<sub>3</sub> standard to 70 ppb. In doing so, she is selecting a primary O<sub>3</sub> standard that is requisite to protect public health with an adequate margin of safety, in light of her 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 and the appropriate inferences to be drawn therefrom.

The Administrator’s decision to revise the level of the primary O<sub>3</sub> standard to 70 ppb builds upon her conclusion that the overall body of scientific evidence and exposure/risk information calls into question the adequacy of public health protection afforded by the current standard, particularly for at-risk populations and lifestages (II.B.3).<sup>148</sup> Consistent with the proposal, her decision on level places the greatest emphasis on the results of controlled human exposure studies and on quantitative analyses based on information from these studies, particularly analyses of O<sub>3</sub> exposures of concern. As in the proposal, and as discussed further below, she views the results of the lung function risk assessment, analyses of O<sub>3</sub> air quality in

locations of epidemiologic studies, and epidemiology-based quantitative health risk assessments as providing information in support of her decision to revise the current standard, but a more limited basis for selecting a particular standard level among a range of options. See *Mississippi*, 744 F. 3d at 1351–52 (studies can legitimately support a decision to revise the standard, but not provide sufficient information to justify their use in setting the level of a revised standard).

Given her consideration of the evidence, exposure/risk information, advice from CASAC, and public comments, the Administrator judges that a standard with a level of 70 ppb is requisite to protect public health with an adequate margin of safety. She notes that the determination of what constitutes an adequate margin of safety is expressly left to the judgment of the EPA Administrator. See *Lead Industries Association v. EPA*, 647 F.2d at 1161–62; *Mississippi*, 744 F. 3d at 1353. She further notes that in evaluating how particular standards address the requirement to provide an adequate margin of safety, it is appropriate to 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 present (I.B, above). Consistent with past practice and long-standing judicial precedent, the Administrator 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.<sup>149</sup>

In considering the need for an adequate margin of safety, the Administrator notes that a standard with a level of 70 ppb O<sub>3</sub> would be expected to provide substantial improvements in public health, including for at-risk groups such as children and people with asthma. The following paragraphs summarize the basis for the Administrator’s conclusion that a revised primary O<sub>3</sub> standard with a level of 70 ppb is requisite to protect the public health with an adequate margin of safety.

As an initial matter, consistent with her conclusions on the need for revision of the current standard (II.B.3), in reaching a decision on level the Administrator places the most weight on information from controlled human exposure studies. In doing so, she notes that controlled human exposure studies provide the most certain evidence indicating the occurrence of health

<sup>147</sup> As discussed above (II.C.4.b.i), when commenting on the extent to which the study by Schelegle *et al.* (2009) suggests the potential for adverse effects following O<sub>3</sub> exposures below 72 ppb, CASAC stated the following: “[I]f subjects had been exposed to ozone using the 8-hour averaging period used in the standard [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” (Frey, 2014c, p. 5).

<sup>148</sup> 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.

<sup>149</sup> See, *e.g.* *NRDC v. EPA*, 902 F. 2d 962, 973–74 (D.C. Cir. 1990).

effects in humans following specific O<sub>3</sub> exposures. In particular, she notes that the effects reported in controlled human exposure studies are due solely to O<sub>3</sub> 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). The Administrator also observes that her emphasis on information from controlled human exposure studies is consistent with CASAC's advice and interpretation of the scientific evidence (Frey, 2014c).

With regard to the effects shown in controlled human exposure studies following specific O<sub>3</sub> exposures, as discussed in more detail above (II.B, II.C.4.b.i), the Administrator notes that (1) the largest respiratory effects, and the broadest range of effects, have been studied and reported following exposures to 80 ppb O<sub>3</sub> or higher (*i.e.*, decreased lung function, increased airway inflammation, increased respiratory symptoms, AHR, and decreased lung host defense); (2) exposures to O<sub>3</sub> concentrations as low as 72 ppb have been shown to both decrease lung function and result in respiratory symptoms; and (3) exposures to O<sub>3</sub> concentrations as low as 60 ppb have been shown to decrease lung function and to increase airway inflammation.

While such controlled human exposure studies provide a high degree of confidence regarding the occurrence of health effects following exposures to O<sub>3</sub> concentrations from 60 to 80 ppb, there are no universally accepted criteria by which to judge the adversity of the observed effects. To inform her judgments on the potential adversity to public health of effects reported in controlled human exposure studies, the Administrator considers ATS recommendations and CASAC advice, as described in detail above (II.B.2, II.C.4.b.i, II.C.4.b.iii, II.C.4.b.iv). Based on her consideration of such recommendations and advice, the Administrator is confident that the respiratory effects that have been observed following exposures to 72 ppb O<sub>3</sub> or above can be adverse. In addition, she judges that adverse effects are likely to occur following exposures somewhat below 72 ppb (II.C.4.b.i). However, as described above (II.C.4.b.i, II.C.4.b.iii, II.C.4.b.iv), the Administrator is notably less confident in the adversity to public health of the respiratory effects that have been observed following exposures to O<sub>3</sub> concentrations as low as 60 ppb, given her consideration of the following: (1) ATS recommendations indicating uncertainty in judging adversity based

on lung function decrements alone; (2) uncertainty in the extent to which a short-term, transient population-level decrease in FEV<sub>1</sub> would increase the risk of other, more serious respiratory effects in that population (*i.e.*, per ATS recommendations on population-level risk); and (3) compared to 72 ppb, CASAC advice is less clear regarding the potential adversity of effects at 60 ppb.

Taken together, the Administrator concludes that the evidence from controlled human exposure studies provides strong support for her conclusion that a revised standard with a level of 70 ppb is requisite to protect the public health with an adequate margin of safety. She bases this conclusion, in part, on the fact that such a standard level would be well below the O<sub>3</sub> exposure concentration shown to result in the widest range of respiratory effects (*i.e.*, 80 ppb), and below the lowest O<sub>3</sub> exposure concentration shown to result in the adverse combination of lung function decrements and respiratory symptoms (*i.e.*, 72 ppb). See *Lead Industries*, 647 F. 2d at 1160 (setting NAAQS at level well below the level where the clearest adverse effects occur, and at a level eliminating most "sub-clinical effects" provides an adequate margin of safety).

As discussed above (II.C.4.b.i), the Administrator also notes that a revised O<sub>3</sub> standard with a level of 70 ppb can provide substantial protection against the broader range of O<sub>3</sub> exposure concentrations that have been shown in controlled human exposure studies to result in respiratory effects, including exposure concentrations below 70 ppb. 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) and, in the case of the fourth-high form of the revised primary O<sub>3</sub> standard (II.C.3), the large majority of days in areas that meet the revised standard will have 8-hour O<sub>3</sub> concentrations below 70 ppb, with most days having 8-hour O<sub>3</sub> concentrations well below this level. In addition, the degree of protection provided by the O<sub>3</sub> NAAQS is also dependent on the extent to which people experience health-relevant O<sub>3</sub> exposures in locations meeting the NAAQS. As discussed above, for a pollutant like O<sub>3</sub> where adverse responses are critically dependent on ventilation rates, the Administrator notes that it is important to consider activity patterns in the exposed population. Not considering activity patterns, and corresponding ventilation rates, can result in a standard that provides more protection than is requisite. Therefore, as discussed in the

proposal, in considering the degree of protection provided by a revised primary O<sub>3</sub> standard, the Administrator considers the extent to which that standard would be expected to limit population exposures of concern (*i.e.*, which take into account activity patterns and estimated ventilation rates) to the broader range of O<sub>3</sub> exposure concentrations shown to result in health effects.

Due to interindividual variability in responsiveness, the Administrator notes that not every occurrence of an exposure of concern will result in an adverse effect (II.C.4.b.i). Moreover, repeated occurrences of some of the effects demonstrated following exposures of concern could increase the likelihood of adversity (U.S. EPA, 2013, Section 6.2.3, p. 6–76). In particular, she notes that the types of respiratory effects that can occur following exposures of concern, particularly if experienced repeatedly, provide a plausible mode of action by which O<sub>3</sub> may cause other more serious effects. Therefore, as in the proposal, the Administrator is most concerned about protecting at-risk populations against repeated occurrences of exposures of concern. In considering the appropriate metric for evaluating repeated occurrences of exposures of concern, the Administrator acknowledges that it is not clear from the evidence, or from the ATS recommendations, CASAC advice, or public comments, how particular numbers of exposures of concern could impact the seriousness of the resulting effects, especially at lower exposure concentrations. Therefore, the Administrator judges that focusing on HREA estimates of two or more exposures of concern provides a health-protective approach to considering the potential for repeated occurrences of exposures of concern that could result in adverse effects.

Based on her consideration of adversity discussed above, the Administrator places the most emphasis on setting a standard that appropriately limits repeated occurrences of exposures of concern at or above the 70 and 80 ppb benchmarks. She notes that a revised standard with a level of 70 ppb is estimated to eliminate the occurrence of two or more exposures of concern to O<sub>3</sub> concentrations at or above 80 ppb and to virtually eliminate the occurrence of two or more exposures of concern to O<sub>3</sub> concentrations at or above 70 ppb for all children and children with asthma, even in the worst-case year and location evaluated.

While she is less confident that adverse effects will occur following exposures to O<sub>3</sub> concentrations as low as 60 ppb, as discussed above, the

Administrator judges that it is also appropriate to consider estimates of exposures of concern for the 60 ppb benchmark. Consistent with this judgment, although CASAC advice regarding the potential adversity of effects at 60 ppb was less definitive than for effects at 72 ppb, CASAC did clearly advise the EPA to consider the extent to which a revised standard is estimated to limit the effects observed following 60 ppb exposures (Frey, 2014c). Therefore, the Administrator considers estimated exposures of concern for the 60 ppb benchmark, particularly considering the extent to which the health protection provided by a revised standard includes a margin of safety against the occurrence of adverse O<sub>3</sub>-induced effects. The Administrator notes that a revised standard with a level of 70 ppb is estimated to protect the vast majority of children in urban study areas (*i.e.*, about 96% to more than 99% of children in individual 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%.

Given the considerable protection provided against repeated exposures of concern for all of the benchmarks evaluated, including the 60 ppb benchmark, the Administrator judges that a standard with a level of 70 ppb will incorporate a margin of safety against the adverse O<sub>3</sub>-induced effects shown to occur following exposures at or above 72 ppb, and judged likely to occur following exposures somewhat below 72 ppb.

While the Administrator is less concerned about single occurrences of O<sub>3</sub> exposures of concern, especially for the 60 ppb benchmark, she judges that estimates of one or more exposures of concern can provide further insight into the margin of safety provided by a revised standard. In this regard, she notes that a standard with a level of 70 ppb is estimated to (1) virtually eliminate all occurrences of exposures of concern at or above 80 ppb; (2) protect the vast majority of children in urban study areas from experiencing any exposures of concern at or above 70 ppb (*i.e.*,  $\geq$  about 99%, based on mean estimates; Table 1); and (3) to achieve substantial reductions, compared to the current standard, in the occurrence of one or more exposures of concern at or above 60 ppb (*i.e.*, about a 50% reduction; Table 1). The Administrator judges that these results provide further support for her conclusion that a standard with a level of 70 ppb will incorporate an adequate margin of safety against the occurrence of O<sub>3</sub> exposures

that can result in effects that are adverse to public health.

The Administrator additionally judges that a standard with a level of 70 ppb would be expected to result in important reductions, compared to the current standard, in the population-level risk of O<sub>3</sub>-induced lung function decrements ( $\geq 10\%$ ,  $\geq 15\%$ ) in children, including children with asthma. Specifically, a revised standard with a level of 70 ppb is estimated to reduce the risk of two or more O<sub>3</sub>-induced decrements by about 30% and 20% for decrements  $\geq 15$  and 10%, respectively (Table 2, above). However, as discussed above (II.C.4.b.i), the Administrator judges that there are important uncertainties in using lung function risk estimates as a basis for considering the occurrence of adverse effects in the population given (1) the ATS recommendation that “a small, transient loss of lung function, by itself, should not automatically be designated as adverse” (ATS, 2000a); (2) uncertainty in the extent to which a transient population-level decrease in FEV<sub>1</sub> would increase the risk of other, more serious respiratory effects in that population (*i.e.*, per ATS recommendations on population-level risk); and (3) that CASAC did not advise considering a standard that would be estimated to eliminate O<sub>3</sub>-induced lung function decrements  $\geq 10$  or 15% (Frey, 2014c). Moreover, as at proposal, the Administrator notes that 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).<sup>150</sup> Given this, and the resulting considerable overlap between the ranges of lung function risk estimates for different standard levels, the Administrator puts limited weight on the lung function risk estimates for distinguishing between the degrees of public health protection provided by alternative standard levels. Therefore, the Administrator judges that while a standard with a level of 70 ppb would be expected to result in important reductions, compared to the current standard, in the population-level risk of O<sub>3</sub>-induced lung function decrements ( $>10\%$ , 15%) in children, including children with asthma, she also judges that estimated risks of O<sub>3</sub>-induced lung function decrements provide a more limited basis than exposures of concern for distinguishing between the

<sup>150</sup> For example, the average percentage of children estimated to experience two or more decrements  $\geq 10\%$  ranges from approximately 6 to 11% for a standard level of 70 ppb, up to about 9% for a level of 65 ppb, and up to about 6% for a level of 60 ppb (Table 2, above).

appropriateness of the health protection afforded by a standard level of 70 ppb versus lower levels.

The Administrator also considers the epidemiologic evidence and the quantitative risk estimates based on information from epidemiologic studies. As discussed in the proposal, and above in the EPA's responses to significant comments, although the Administrator acknowledges the important uncertainties in using the O<sub>3</sub> epidemiologic studies as a basis for selecting a standard level, she notes that these studies can provide perspective on the degree to which O<sub>3</sub>-associated health effects have been identified in areas with air quality likely to have met various standards. Specifically, the Administrator notes analyses in the PA (U.S. EPA, 2014c, section 4.4.1) indicating that a revised standard with a level of 70 ppb would be expected to require additional reductions, beyond those required by the current standard, in the short- and long-term ambient O<sub>3</sub> concentrations that provided the basis for statistically significant O<sub>3</sub> health effect associations in both the single-city and multicity epidemiologic studies evaluated. As discussed above in the response to comments, while the Administrator concludes that these analyses support a level at least as low as 70 ppb, based on a study reporting health effect associations in a location that met the current standard over the entire study period but that would have violated a revised standard with a level of 70 ppb,<sup>151</sup> she further judges that they are of more limited utility for distinguishing between the appropriateness of the health protection estimated for a standard level of 70 ppb and the protection estimated for lower levels. Thus, the Administrator notes that a revised standard with a level of 70 ppb will provide additional public health protection, beyond that provided by the current standard, against the clearly adverse effects reported in

<sup>151</sup> As discussed above (II.B.2.c.ii and II.B.3), the study by Mar and Koenig (2009) reported positive and statistically significant associations with respiratory emergency department visits in a location that would have met the current standard over the entire study period, but violated a standard with a level of 70 ppb. In addition, air quality analyses in the locations of two additional studies highlighted in sections II.B.2 and II.B.3 (Silverman and Ito, 2010; Strickland *et al.*, 2010) were used in the PA to inform staff conclusions on the adequacy of the current primary O<sub>3</sub> standard. However, they did not provide insight into the appropriateness of standard levels below 75 ppb and, therefore, these analyses were not used to inform conclusions on potential alternative standard levels lower than 75 ppb (U.S. EPA, 2014c, Chapters 3 and 4). See *Mississippi*, 744 F. 3d at 1352–53 (study appropriate for determining causation may not be probative for determining level of a revised standard).

epidemiologic studies. She judges that a standard with a level of 70 ppb strikes an appropriate balance between setting the level to require reductions in the ambient O<sub>3</sub> concentrations associated with statistically significant health effects in epidemiologic studies, while not being more protective than necessary in light of her considerable uncertainty in the extent to which studies clearly show O<sub>3</sub>-attributable effects at lower ambient O<sub>3</sub> concentrations. This judgment is consistent with the Administrator's conclusions based on information from controlled human exposure studies, as discussed above.

With regard to epidemiology-based risk estimates, the Administrator takes note of 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). While she concludes that epidemiology-based risk analyses provide only limited support for any specific standard level, consistent with CASAC advice the Administrator judges that, compared to the current standard, a revised standard with a level of 70 ppb will result in meaningful reductions in the mortality and respiratory morbidity risk that is associated with short-or long-term ambient O<sub>3</sub> concentrations.

Given all of the evidence and information discussed above, the Administrator judges that a standard with a level of 70 ppb is requisite to protect public health with an adequate margin of safety, and that a level below 70 ppb would be more than "requisite" to protect the public health. In reaching this conclusion, she notes that a decision to set a lower level would place a large amount of emphasis on the potential public health importance of (1) further reducing the occurrence of O<sub>3</sub> exposures of concern, though the exposures about which she is most concerned are estimated to be almost eliminated with a level of 70 ppb, and lower levels would be expected to achieve virtually no additional reductions in these exposures (see Table 1, above); (2) further reducing the risk of O<sub>3</sub>-induced lung function decrements >10 and 15%, despite having less confidence in judging the potential adversity of lung function decrements alone and the considerable overlap between risk estimates for various standard levels that make it difficult to distinguish between the risk reductions achieved; (3) further reducing ambient O<sub>3</sub> concentrations, relative to those in

locations of epidemiologic studies, though associations have not been reported for air quality that would have met a standard with a level of 70 ppb across all study locations and over entire study periods, and despite her consequent judgment that air quality analyses in epidemiologic study locations are not informative regarding the additional degree of public health protection that would be afforded by a standard set at a level below 70 ppb; and (4) further reducing epidemiology-based risk estimates, despite the important uncertainties in those estimates. As discussed in this section and in the responses to significant comments above, 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 70 ppb O<sub>3</sub>. Compared to an O<sub>3</sub> standard level of 70 ppb, the Administrator concludes that the extent to which lower standard levels could result in further public health improvements becomes notably less certain.

Thus, having carefully considered the evidence, information, CASAC advice, and public comments relevant to her decision on the level of the primary O<sub>3</sub> standard, as discussed above and in the Response to Comments document, the Administrator is revising the level of the primary O<sub>3</sub> standard to 70 ppb. She is mindful that the selection of a primary O<sub>3</sub> 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 overstate nor understate the strengths and limitations of that evidence and information and the appropriate inferences to be drawn therefrom. Her decision places the greatest emphasis on the results of controlled human exposure studies and on quantitative analyses based on information from these studies, particularly analyses of O<sub>3</sub> exposures of concern. As in the proposal, and as discussed above, she views the results of the lung function risk assessment, analyses of O<sub>3</sub> air quality in locations of epidemiologic studies, and epidemiology-based quantitative health risk assessments as providing information in support of her decision to revise the current standard, but a more limited basis for selecting a particular standard level among a range of options.

In making her decision to revise the level of the primary O<sub>3</sub> standard to 70 ppb, the Administrator judges that a revised standard with a level of 70 ppb

strikes the appropriate balance between limiting the O<sub>3</sub> exposures about which she is most concerned and not going beyond what would be required to effectively limit such exposures. Specifically, the Administrator judges it appropriate to set a standard estimated to eliminate, or almost eliminate, repeated occurrences of exposures of concern for the 70 and 80 ppb benchmarks. She further judges that a lower standard level would not be appropriate given that lower levels would be expected to achieve virtually no additional reductions in repeated occurrences of exposures of concern for these benchmarks. For the 60 ppb benchmark, a level of 70 ppb is estimated to protect the vast majority of children (including children with asthma) in urban study areas from experiencing two or more exposures of concern, reflecting important reductions in such exposures compared to the current standard and indicating that the revised primary O<sub>3</sub> standard provides an adequate margin of safety. Given these results, including the considerable protection provided against repeated exposures of concern for the 60 ppb benchmark, the Administrator judges that a standard with a level of 70 ppb incorporates an adequate margin of safety against the occurrence of adverse O<sub>3</sub>-induced effects.

For all of the above reasons, the Administrator concludes that a primary O<sub>3</sub> standard with an 8-hour averaging time; a 3-year average, fourth-high form; and a level of 70 ppb is requisite to protect public health, including the health of at-risk populations, with an adequate margin of safety. Therefore, in this final rule she is setting the level of the primary O<sub>3</sub> standard at 70 ppb.

#### *D. Decision on the Primary Standard*

For the reasons discussed above, and taking into account information and assessments presented in the ISA, HREA, and PA, the advice and recommendations of the CASAC Panel, and the public comments, the Administrator has decided to revise the existing 8-hour primary O<sub>3</sub> standard. Specifically, the Administrator is revising the level of the primary O<sub>3</sub> standard to 70 ppb. The revised 8-hour primary standard, with a level of 70 ppb, 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<sub>3</sub> concentration is less than or equal to 70 ppb. Data handling conventions are specified in the new Appendix U that is adopted, as discussed in section V below.

At this time, EPA is also promulgating revisions to the Air Quality Index (AQI) for O<sub>3</sub> to be consistent with the revisions to the primary O<sub>3</sub> standard and the health information evaluated in this review of the standards. These revisions are discussed below in section III.

### 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 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. 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.<sup>152</sup> See CAA section 127. 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<sub>3</sub>, CO, NO<sub>2</sub>, PM and SO<sub>2</sub>. 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 2008 O<sub>3</sub> 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 selecting breakpoints is for each category to span at least a 15 ppb range to allow for more accurate air pollution 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.

#### A. Proposed Revisions to the AQI

Recognizing the importance of revising the AQI in a timely manner to be consistent with any revisions to the NAAQS, EPA proposed conforming changes to the AQI, in connection with the Agency's proposed decision on revisions to the O<sub>3</sub> NAAQS. These conforming changes included setting the 100 level of the AQI at the same level as the revised primary O<sub>3</sub> 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 did 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 proposed to revise the AQI for O<sub>3</sub> by setting an AQI value of 100 equal to the level of the revised O<sub>3</sub> standard (65–70 ppb). The EPA also proposed 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 proposed 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 took 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 young, healthy adults exposed to O<sub>3</sub> while engaged in quasi-continuous moderate exercise for 6.6 hours to cause moderate lung function decrements (*i.e.*, FEV<sub>1</sub> decrements ≥ 10%, which could be adverse to people with lung disease) and airway inflammation.<sup>153</sup> The EPA proposed 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 young, healthy adults indicate that up to 25% of exposed people are likely to have moderate lung function decrements (*i.e.*, 25% have FEV<sub>1</sub> decrements ≥ 10%; 12% have FEV<sub>1</sub> decrements ≥ 15%) and up to 7% are likely to have large lung function decrements (*i.e.*, FEV<sub>1</sub> decrements ≥ 20%) (McDonnell *et al.*, 2012; Figure 7). Large lung function decrements would likely interfere with normal activity for many healthy people. For most people with lung disease, large lung function decrements would not only interfere with normal activity but would increase the likelihood that they would seek medical treatment (72 FR 37850, July 11, 2007). The EPA proposed 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 young, healthy adults indicate that up to 38% of exposed people are likely to have moderate lung function decrements (*i.e.*, 38% have FEV<sub>1</sub> decrements ≥ 10%; 22% have FEV<sub>1</sub> decrements ≥ 15%) and up to 13% are likely to have large lung function decrements (*i.e.*, FEV<sub>1</sub> decrements ≥ 20%). The EPA proposed 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<sub>1</sub> decrements ≥ 20%), which would interfere with daily activities for many of them and likely cause people with lung disease to seek medical attention.

EPA stated that the proposed breakpoints reflect an appropriate balance between reflecting the health evidence that is the basis for the proposed primary O<sub>3</sub> standard and providing category ranges that are large enough to be forecasted accurately, so

<sup>152</sup> EPA issued the AQI in 1999, updating the previous Pollutant Standards Index (PSI) to send "a clear and consistent message to the public by providing nationally uniform information on air quality." The rule requires metropolitan areas of 350,000 and larger to report the AQI [and associated health effects] daily; all other AQI-related activities—including real-time ozone and particle pollution reporting, next-day air quality forecasting and action days—are voluntary and are carried out at the discretion of state, local and tribal air agencies. In the 1999 rule, we acknowledged these other programs, noting, for example, that while states primarily use the AQI "to provide general information to the public about air quality and its relationship to public health," some state, local or tribal agencies use the index to call "action days." Action days encourage additional steps, usually voluntary, that the public, business or industry could take to reduce emissions when higher levels of pollution are forecast to occur. As the 1999 rule notes, agencies may have several motivations for calling action days, including: providing health information to the public; attaining or maintaining NAAQS attainment status; meeting specific emission reduction targets; and managing or reducing traffic congestion. State, local and tribal agencies should consider whether non-voluntary emissions or activity curtailments are necessary (as opposed to a suite of voluntary measures) for days when the AQI is forecasted to be on the lower end of the moderate category.

<sup>153</sup> 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).

that the new AQI for O<sub>3</sub> can be implemented more easily in the public forum for which the AQI ultimately exists. However, the EPA recognized alternative approaches to viewing the evidence and information and solicited comment on the proposed revisions to the AQI.

With respect to reporting requirements (40 CFR part 58, section 58.50), EPA proposed to revise 40 CFR part 58, section 58.50 (c) to determine the areas subject to AQI reporting requirements based on the latest available census figures, rather than the most recent decennial U.S. census.<sup>154</sup> This change is consistent with our current practice of using the latest population figures to make monitoring requirements more responsive to changes in population.

#### B. Comments on Proposed Revisions to the AQI

EPA received many comments on the proposed changes to the AQI. Three issues came up in the comments, including: (1) Whether the AQI should be revised at all, even if the primary standard is revised; (2) whether an AQI value of 100 should be set equal to the level of the primary standard and the other breakpoints adjusted accordingly; and, (3) whether the AQI reporting requirements should be based on the latest available census figures rather than the most recent decennial census.

With respect to the first issue, some industry commenters stated that the AQI should not be revised at all, even if the level of the primary O<sub>3</sub> standard is revised. In support of this position, these commenters stated that the proposed conforming changes to the AQI would lower O<sub>3</sub> levels in each category, and would mean that air quality that is actually improving would be reported as less healthy. According to commenters, the revised AQI would fail to capture these improvements and potentially mislead the public into thinking that air quality has degraded and that EPA and state regulators are not doing their jobs. These commenters noted that there is no requirement to revise the AQI, and that the CAA does not tie the AQI to the standards, stating that the purpose of section 319(a) of the CAA is to provide a consistent, uniform means of gauging air quality. These commenters further asserted that EPA's proposed changes run counter to that uniformity by changing the air quality significance of a given index value and category and that retention of the

current AQI breakpoints would allow continued uniform information on air quality. Commenters stated that it is important that the EPA clearly communicate that the immediate increases in moderate rated days are due to AQI breakpoint adjustment and not due to a sudden decline in air quality. One commenter estimated the increased proportion of days in the moderate category and above in 10 metropolitan areas for 2013 and also for 2025 for 4 cities from the original 10 that were estimated to attain a standard below 70 ppb, to compare with 2013. This commenter noted that the change in the proposed AQI breakpoint between "good" and "moderate" would result in a larger number of days that did not meet the "good" criteria. They went further to claim that the change in breakpoints would result in fewer "good" days in the year 2025 (using the new breakpoint) than occurred in 2013 (using the old breakpoints) despite substantial improvement in air quality over that time period.

On the other hand, state and local agencies and their organizations, environmental and medical groups, and members of the public overwhelmingly supported revising the AQI when the level of the standard is revised. Even state agencies that did not support revising the standard, expressed support for revising the AQI at the same time as the standard, if the standard is revised.

Recognizing the importance of the AQI as a communication tool that allows members of the public to take exposure reduction measures when air quality poses health risks, the EPA agrees with these comments about revising the AQI at the same time as the primary standard. The EPA agrees with state and local agency commenters that its historical approach of setting an AQI value of 100 equal to the level of the revised 8-hour primary O<sub>3</sub> standard is appropriate, both from a public health and a communication perspective.

EPA disagrees with commenters who stated that the AQI should not be linked to the primary standards. As noted in the August 4, 1999, rulemaking (64 FR 149, 42531) that established the current AQI, the EPA established the nationally uniform air quality index, called the Pollutant Standards Index (PSI), in 1976 to meet the needs of state and local agencies with the following advantages: It sends a clear and consistent message to the public by providing nationally uniform information on air quality; it is keyed as appropriate to the NAAQS and the Significant Harm Level which have a scientific basis relating air quality and public health; it is simple and easily understood by the public; it provides a

framework for reflecting changes to the NAAQS; and it can be forecasted to provide advance information on air quality. Both the PSI and AQI have historically been normalized across pollutants by defining an index value of 100 as the numerical level of the short-term (*i.e.*, averaging time of 24-hours or less) primary NAAQS for each pollutant. Moreover, this approach does not mislead the public. Since the establishment of the AQI, the EPA and state and local air agencies and organizations have developed experience in educating the public about changes in the standards and, concurrently, related changes to AQI breakpoints and advisories. When the standards change, EPA and state and local agencies have tried to help the public understand that air quality is not getting worse, it's that the health evidence underlying the standards and the AQI has changed. EPA's Air Quality System (AQS), the primary repository for air quality monitoring data, is also adjusted to reflect the revised breakpoints. Specifically, all historical AQI values in AQS are recomputed with the revised breakpoints, so that all data queries and reports downstream of AQS will show appropriate trends in AQI values over time.<sup>155</sup>

In general, commenters who supported revising the AQI when the standard is revised, also supported setting an AQI value of 100 equal to the level of the 8-hour primary O<sub>3</sub> standard. The EPA agrees with these commenters. With respect to an AQI value of 100, the EPA is taking final action to set an AQI value of 100 equal to the level of the 8-hour primary standard at 70 ppb O<sub>3</sub>.

With respect to proposed changes to other AQI breakpoints, some state and local agency commenters expressed general support for all the changes in O<sub>3</sub> breakpoints (in Table 2 of Appendix G). In addition, we received a few comments specifically about the breakpoint between the good and moderate categories. One state expressed the view that forecasting the AQI for O<sub>3</sub> is not an exact science, so it is important to provide a range large enough to reasonably predict O<sub>3</sub>

<sup>155</sup> Although we do not contest the assertion that the new AQI breakpoints will lead to fewer green days in the near future, we do not agree that commenters' analysis sufficiently demonstrates that there would be fewer green days in 2025 than in 2013. In their analysis, they compared observed 2013 data with modeled 2025 data without doing any model performance evaluation for AQI categories or comparison of current year modeled and observed data. The current year observations are not directly comparable to the future-year modeling data without some such evaluation and, as such, we cannot support their quantitative conclusions.

<sup>154</sup> Under 40 CFR 58.50, any MSA with a population exceeding 350,000 is required to report AQI data.

concentrations for the following day ( $\geq$  20 ppb). Although not supporting revision of the standard, this state recommended that if the primary standard was revised to 70 ppb, the lower end of moderate category should be set at 50 ppb to allow for a 20 ppb spread in that category. Several commenters recommending a breakpoint between the good and moderate categories of no higher than 50 ppb stated that this breakpoint should be set on health information, pointing to epidemiologic data and the World Health organization guidelines. The Agency agrees that AQI breakpoints should take into consideration health information when possible, and also that it is important for AQI categories to span ranges large enough to support accurate forecasting. The EPA is setting the breakpoint at the lower end of the moderate category at 55 ppb, which is 15 ppb below the level of the standard of 70 ppb. This is consistent with past practice of making a proportional adjustment to this AQI breakpoint, relative to an AQI value of 100 (*i.e.*, 70 ppb), and also retains the current practice of providing a 15 ppb range in the moderate category to allow for accurate forecasting. This level is below the lowest concentration (*i.e.*, 60 ppb) that has been shown in controlled human exposure studies of healthy adults to cause moderate lung function decrements (*i.e.*, FEV<sub>1</sub> decrements  $\geq$  10%, which could be adverse to people with lung disease), large lung function decrements (*i.e.*, FEV<sub>1</sub> decrements  $\geq$  20%) in a small proportion of people, and airway inflammation, notwithstanding the Administrator's judgment that there is uncertainty in the adversity of the effects shown to occur at 60 ppb.

We received fewer comments on proposed changes to the AQI values of 150, 200 and 300. Again, some state and local agency commenters expressed general support for proposed changes to the AQI. Some states specifically supported these breakpoints. However, a commenter suggested setting an AQI value at the lower end of the unhealthy category, at a level much lower than 85 ppb, since they state that it is a key threshold that is often used in air quality action day programs as a trigger to encourage specific behavior modifications or reduce emissions of O<sub>3</sub> precursors (*e.g.*, by taking public transportation to work). This commenter stated that setting the breakpoint at 85 ppb would, in the Agency's own rationale, not require the triggering of these pollution reduction measures until air quality threatened to impact

25% of people exposed. We disagree with this commenter because EPA does not have any requirements for voluntary programs. State and local air agencies have discretion to set the trigger for voluntary action programs at whatever level they choose, and they are currently set at different levels, not just at the unhealthy breakpoint specified in the comment. For example, Houston, Galveston and Brazoria TX metropolitan area calls ozone action days when air quality reaches the unhealthy for sensitive groups category. For more information about action days programs across the U.S. see the AirNow Web site ([www.airnow.gov](http://www.airnow.gov)) and click on the link to AirNow Action Days. The unhealthy category represents air quality where there are general population-level effects. We believe that setting the breakpoint between the unhealthy for sensitive groups and unhealthy categories, at 85 ppb where, as discussed in section IIIA above, controlled human exposure studies of young, healthy adults exposed to O<sub>3</sub> while engaged in quasi-continuous moderate exercise for 6.6 hours indicate that up to 25% of exposed people are likely to have moderate lung function decrements and up to 7% are likely to have large lung function decrements (McDonnell *et al.*, 2012; Figure 7) is appropriate. A smaller proportion of inactive or less active individuals would be expected to experience lung function decrements at 85 ppb. Moreover, a breakpoint at 85 ppb allows for category ranges large enough for accurate forecasting. Accordingly, the EPA is adopting the proposed revisions to the AQI values of 150, 200 and 300.

As noted earlier, the EPA proposed to revise 40 CFR part 58, section 58.50(c) to determine the areas subject to AQI reporting requirements based on the latest available census figures, rather than the most recent decennial U.S. census.

A total of five state air monitoring agencies provided comments on this proposed change. Four agencies supported the proposal. One state commenter did not support the proposal, noting that the change would unnecessarily complicate AQI reporting and possibly increase reporting burdens in an unpredictable manner.

The EPA notes that the majority of monitoring network minimum requirements listed in Appendix D to Part 58 include a reference to "latest available census figures." Minimum network requirements for O<sub>3</sub>, PM<sub>2.5</sub>, SO<sub>2</sub>, and NO<sub>2</sub> all include this language in the regulatory text and monitoring agencies have successfully adopted these processes into their planning

activities and the subsequent revision of their annual monitoring network plans which are posted for public review. Annual population estimates are easily obtainable from the U.S. Census Bureau and the EPA does not believe the burden in tracking these annual estimates is excessive or complicated.<sup>156</sup> Although the changes in year to year estimates are typically modest, there are MSAs that are approaching (or have recently exceeded) the 350,000 population AQI reporting limit and there is great value in having the AQI reported for these areas when the population threshold is exceeded versus waiting potentially up to 10 years for a revision to the decennial census. Accordingly, the EPA is finalizing the proposed revision to 40 CFR part 58, section 58.50(c) to require the AQI reporting requirements to be based on the latest available census figures.

One state requested additional guidance on the frequency of updating the AQI reporting threshold, and recommended linking the AQI reporting requirement evaluation with the annual air monitoring network plan requirements, and recommended requiring AQI reporting to begin no later than January 1 of the following year. The EPA notes that the census bureau estimates appear to be released around July 1 of each year which would not provide sufficient time for monitoring agencies to incorporate AQI reporting in their annual plans for that year, which are also due by July 1 each year. EPA believes that it should be unnecessary for monitoring agencies to wait until the implementation of the following year's annual plan (*i.e.*, approximately 18 months later) to begin AQI reporting. Accordingly, EPA is not at this time including a specific deadline for commencement of AQI reporting for newly-subject areas in 40 CFR part 58, but will work with agencies to implement additional AQI reporting as needed to ensure that information is being disseminated in a timely fashion.

### C. Final Revisions to the AQI

For the reasons discussed above, the EPA is revising the AQI for O<sub>3</sub> by setting an AQI value of 100 equal to 70 ppb, 8-hour average, the level of the revised primary O<sub>3</sub> standard. The EPA is also revising the following breakpoints: An AQI value of 50 is set at 54 ppb; an AQI value of 150 is set at 85 ppb; an AQI value of 200 is set at 105 ppb; and an AQI value of 300 is set at 200 ppb. All of these levels are averaged over 8 hours. The revisions to all of the

<sup>156</sup> <http://www.census.gov/popest/data/metro/totals/2014/CBSA-EST2014-alldata.html>.



breakpoints are based on estimated health outcomes at relevant ambient concentrations and to allow for each category to span at least a 15–20 ppb category range to allow for more accurate air pollution forecasting. The EPA believes that the revised breakpoints provide a balance between adjustments to reflect the health information supporting the revised O<sub>3</sub> standard and providing category ranges that are large enough to be forecasted accurately, so that the AQI can be implemented more easily in the public forum for which the AQI ultimately exists. With respect to AQI reporting requirements (40 CFR part 58, section 58.50), the EPA is revising 40 CFR part 58, section 58.50(c) to make the AQI reporting requirements 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.

#### IV. Rationale for Decision on the Secondary Standard

##### A. Introduction

This section (IV) presents the rationale for the Administrator's decisions regarding the need to revise the current secondary standard for O<sub>3</sub>, and the appropriate revision. Based on her consideration of the full body of welfare effects evidence and related analyses, including the evidence of effects associated with cumulative seasonal exposures of the magnitudes allowed by the current standard, the Administrator has concluded that the current secondary standard for O<sub>3</sub> does not provide the requisite protection of public welfare from known or anticipated adverse effects. She has decided to revise the level of the current secondary standard to 0.070 ppm, in conjunction with retaining the current indicator, averaging time and form.

The Administrator has made this decision based on judgments regarding the currently available welfare effects evidence, the appropriate degree of public welfare protection for the revised standard, and currently available air quality information on seasonal cumulative exposures that may be allowed by such a standard. In so doing, she has focused on O<sub>3</sub> effects on tree seedling growth as a proxy for the full array of vegetation-related effects of O<sub>3</sub>, ranging from effects on sensitive species to broader ecosystem-level effects. Using this proxy in judging effects to public welfare, the Administrator has concluded that the requisite protection

from adverse effects to public welfare will be provided by a standard that limits cumulative seasonal exposures to 17 ppm-hrs or lower, in terms of a 3-year W126 index, in nearly all instances, and she has also concluded that such control of cumulative seasonal exposures may be achieved by revising the level of the current standard to 70 ppb. Based on all of these considerations, the Administrator has decided that a secondary standard with a level of 0.070 ppm, and the current form and averaging time, will provide the requisite protection of public welfare from known or anticipated adverse effects.

As discussed more fully below, this decision is based on a thorough review, in the ISA, of the latest scientific information on O<sub>3</sub>-induced environmental effects. This decision also takes into account (1) staff assessments in the PA of the most policy-relevant information in the ISA regarding evidence of adverse effects of O<sub>3</sub> to vegetation and ecosystems, information on biologically-relevant exposure metrics, WREA analyses of air quality, exposure, and ecological risks and associated ecosystem services, and staff analyses of relationships between levels of a W126-based metric and a metric based on the form and averaging time of the current standard summarized in the PA and in the proposal notice; (2) CASAC advice and recommendations; and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately, and on the proposal notice.

This decision draws on the ISA's integrative synthesis of the entire body of evidence, generally published through July 2011, on environmental effects associated with the presence of O<sub>3</sub> and related photochemical oxidants in the ambient air (U.S. EPA, 2013, ISA chapters 9–10), and includes more than four hundred new studies that build on the extensive evidence base from the last review. In addition to reviewing the most recent scientific information as required by the CAA, this rulemaking incorporates the EPA's response to the judicial remand of the 2008 secondary O<sub>3</sub> standard in *State of Mississippi v. EPA*, 744 F. 3d 1334 (D.C. Cir. 2013) and, in accordance with the court's decision in that case, fully explains the Administrator's conclusions as to the level of air quality that provides the requisite protection of public welfare from known or anticipated adverse effects. In drawing conclusions on the secondary standard, the decision described in this rulemaking is a public welfare policy judgment made by the

Administrator. The Administrator's decision draws upon the available scientific evidence for O<sub>3</sub>-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. As described in sections IV.B.3 and IV.C.3 below, such judgments in the context of this review include judgments on the weight to place on the evidence of specific vegetation-related effects estimated to result across a range of cumulative seasonal concentration-weighted O<sub>3</sub> exposures; on 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 on the extent to which such effects in such areas may be considered adverse to public welfare.

Information related to vegetation and ecosystem effects, biologically relevant exposure indices, and vegetation exposure and risk assessments were summarized in sections IV.A through IV.C of the proposal (79 FR at 75314–75329), respectively, and key observations from the proposal are briefly outlined in sections IV.A.1 to IV.A.3 below. Subsequent sections of this preamble provide a more complete discussion of the Administrator's rationale, in light of key issues raised in public comments, for concluding that the current standard is not requisite to protect public welfare from known or anticipated adverse effects (section IV.B), and that it is appropriate to revise the current secondary standard to provide additional public welfare protection by revising the level while retaining the current indicator, form and averaging time (section IV.C). A summary of the final decisions on revisions to the secondary standard is presented in section IV.D.

##### 1. Overview of Welfare Effects Evidence a. Nature of Effects

In the more than fifty years that have followed identification of O<sub>3</sub>'s phytotoxic effects, extensive research has been conducted both in and outside of the U.S. to examine the impacts of O<sub>3</sub> on plants and their associated ecosystems (U.S. EPA, 1978, 1986, 1996a, 2006a, 2013). As was established in prior reviews, O<sub>3</sub> can interfere with carbon gain (photosynthesis) and allocation of carbon within the plant, making fewer carbohydrates 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<sub>3</sub>-related vegetation effects, further contribute to the coherence and consistency of the vegetation effects evidence (U.S. EPA, 2013, chapter 9).

The strongest evidence for effects from O<sub>3</sub> exposure on vegetation is from controlled exposure studies, which “have clearly shown that exposure to O<sub>3</sub> is causally linked to visible foliar injury, decreased photosynthesis, changes in reproduction, and decreased growth” in many species of vegetation (U.S. EPA, 2013, p. 1–15). Such effects at the plant scale can also be linked to an array of effects at larger spatial scales, with the currently available evidence indicating that “ambient O<sub>3</sub> exposures can affect ecosystem productivity, crop yield, water cycling, and ecosystem community composition” (U.S. EPA, 2013, p. 1–15; Chapter 9, section 9.4). The current body of O<sub>3</sub> welfare effects evidence confirms and strengthens support for the conclusions reached in the last review on the nature of O<sub>3</sub>-induced welfare effects and is summarized in the ISA as follows (U.S. EPA, 2013, p. 1–8).

The welfare effects of O<sub>3</sub> 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 assessment of this extensive body of science, the EPA has determined that, with respect to vegetation and ecosystems, a causal relationship exists between exposure to O<sub>3</sub> 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 (U.S. EPA, 2013, Table 1–2). In consideration of the evidence of O<sub>3</sub> 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<sub>3</sub> exposure and the alteration of ecosystem water cycling (U.S. EPA, 2013, section 2.6.3). The evidence is also sufficient to conclude a likely causal relationship between O<sub>3</sub> exposure and the alteration of community composition of some terrestrial ecosystems (U.S. EPA, 2013, section 2.6.5). Related to the effects on vegetation growth, productivity and, to some extent, below-ground biogeochemical cycles, the EPA has additionally determined that a likely causal relationship exists between exposures to O<sub>3</sub> in ambient air and reduced carbon sequestration (also termed carbon storage) in terrestrial ecosystems (U.S. EPA, 2013, p. 1–10 and section 2.6.2). Modeling studies available in this review consistently found negative impacts of O<sub>3</sub> on carbon sequestration, although the severity of impact was influenced by “multiple interactions of biological and environmental factors” (U.S. EPA, 2013, p. 2–39).

Ozone in the troposphere is also a major greenhouse gas and radiative forcing agent,<sup>157</sup> with the ISA formally concluding that “the evidence supports a causal relationship between changes in tropospheric O<sub>3</sub> concentrations and radiative forcing” (U.S. EPA, 2013, p. 1–13 and section 2.7.1). While tropospheric O<sub>3</sub> has been ranked third in importance after carbon dioxide and methane, there are “large uncertainties in the magnitude of the radiative forcing estimate attributed to tropospheric O<sub>3</sub>, making the impact of tropospheric O<sub>3</sub> on climate more uncertain than the effect of the longer-lived greenhouse gases” (U.S. EPA, 2013, p. 2–47). The ISA notes that “[e]ven with these uncertainties, global climate models indicate that tropospheric O<sub>3</sub> has contributed to observed changes in global mean and regional surface temperatures” and concludes that “[a]s a result of such evidence presented in climate modeling studies, there is likely to be a causal relationship between changes in tropospheric O<sub>3</sub> concentrations and effects on climate” (U.S. EPA, 2013, p. 2–47).<sup>158</sup> The ISA additionally states that “[i]mportant

<sup>157</sup> As described in the ISA, “[r]adiative 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” (U.S. EPA, 2013, p. 1–13).

<sup>158</sup> Climate responses, including increased surface temperature, have downstream climate-related ecosystem effects (U.S. EPA, 2013, p. 10–7). As noted in section I.D above, such effects may include an increase in the area burned by wildfires, which, in turn, are sources of O<sub>3</sub> precursor emissions.

uncertainties remain regarding the effect of tropospheric O<sub>3</sub> on future climate change” (U.S. EPA, 2013, p. 10–31).

#### b. Vegetation Effects

Given the strong evidence base and the findings of causal or likely causal relationships with O<sub>3</sub> in ambient air, including the quantitative assessments of relationships between O<sub>3</sub> exposure and occurrence and magnitude of effects, this review has given primary consideration to three main kinds of vegetation effects, some of which contribute to effects at scales beyond the plant level, such as at the ecosystem level and on ecosystem services. The three kinds of effects are addressed below in the following order: 1) Visible foliar injury, 2) impacts on tree growth, productivity and carbon storage, and 3) crop yield loss.

Visible foliar injury resulting from exposure to O<sub>3</sub> has been well characterized and documented over several decades of research on many tree, shrub, herbaceous, and crop species (U.S. EPA, 2013, p. 1–10; U.S. EPA, 2006a, 1996a, 1986, 1978). Ozone-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<sub>3</sub> based on the consistent association established with experimental evidence (U.S. EPA, 2013, p. 1–10). The evidence has found that visible foliar injury occurs only when sensitive plants are exposed to elevated O<sub>3</sub> concentrations in a predisposing environment; a major modifying factor is the amount of available soil moisture during the year (U.S. EPA, 2013, section 9.4.2).

The significance of O<sub>3</sub> 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, 2013, 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, 2013, 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, 2013, section 9.4.2). 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, “[e]xperimental evidence has clearly

established a consistent association of visible injury with O<sub>3</sub> exposure, with greater exposure often resulting in greater and more prevalent injury” (U.S. EPA, 2013, section 9.4.2, p. 9–41).

By far the most extensive field-based dataset of visible foliar injury incidence is that obtained by the U.S. Forest Service Forest Health Monitoring/Forest Inventory and Analysis (USFS FHM/FIA) biomonitoring network program (U.S. EPA, 2013, section 9.4.2.1; Smith, 2012; Coulston *et al.*, 2007). A recently published trend analysis of data from the sites located in 24 states of 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 and soil moisture scenarios (Smith, 2012; U.S. EPA, 2013, section 9.4.2.1). Study results showed that incidence and severity of foliar injury were dependent on local site conditions for soil moisture availability and O<sub>3</sub> exposure (U.S. EPA, 2013, p. 9–41). Although the study indicated that moderate O<sub>3</sub> exposures continued to cause visible foliar injury at sites throughout the study area, there was an overall declining trend in the incidence of visible foliar injury as peak O<sub>3</sub> concentrations declined (U.S. EPA, 2013, p. 9–40).

Ozone has been shown to affect a number of important U.S. tree species with respect to growth, productivity, and carbon storage. Ambient O<sub>3</sub> 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<sub>3</sub>-related effects on forest tree growth, productivity and carbon storage, and further strengthens the support for those conclusions. A variety of factors in natural environments can either mitigate or exacerbate predicted O<sub>3</sub>-plant interactions and are recognized sources of uncertainty and variability. Such factors include multiple genetically influenced determinants of O<sub>3</sub> sensitivity, changing sensitivity to O<sub>3</sub> across vegetative growth stages, co-occurring stressors and/or modifying environmental factors (U.S. EPA, 2013, section 9.4.8). In considering of the available evidence, the ISA states, “previous O<sub>3</sub> AQCDs concluded that there is strong evidence that exposure to O<sub>3</sub> decreases photosynthesis and growth in numerous plant species” and that “[s]tudies published since the 2008

review support those conclusions” (U.S. EPA, 2013, 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<sub>3</sub>-induced effects at the scale of the whole plant 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<sub>3</sub> alters biomass allocation and plant reproduction” (U.S. EPA, 2013, p. 1–10).

The strong evidence of O<sub>3</sub> impacts on trees includes robust exposure-response (E–R) functions for reduced growth, termed relative biomass loss (RBL),<sup>159</sup> in seedlings of 11 species. These functions were developed under the National Health and Environmental Effects Research Laboratory–Western Ecology Division program, a series of experiments that used open top chambers (OTCs) to investigate seedling growth response for a single growing season under a variety of O<sub>3</sub> exposures (ranging from near background to well above current ambient concentrations) and growing conditions (U.S. EPA, 2013, 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<sub>3</sub> 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 responses across a number of different sites and/or years when exposed to varying ambient O<sub>3</sub> exposure conditions. For example, a study conducted in forest stands in the southern Appalachian Mountains during a period when O<sub>3</sub> concentrations exceeded the current standard found that the cumulative effects of O<sub>3</sub> 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<sub>3</sub> year in comparison to a low-O<sub>3</sub> year (U.S. EPA, 2013, section 9.4.3.1; McLaughlin *et al.*, 2007a). The study also reported that

<sup>159</sup> These functions for RBL estimate reduction in a year's growth as a percentage of that expected in the absence of O<sub>3</sub> (U.S. EPA, 2013, section 9.6.2; U.S. EPA, 2014b, section 6.2).

high ambient O<sub>3</sub> concentrations can increase whole-tree water use and in turn reduce late-season streamflow (McLaughlin *et al.*, 2007b; U.S. EPA, 2013, p. 9–43).

The magnitude of O<sub>3</sub> 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), and the sensitivity of co-occurring species and environmental factors (*e.g.*, drought and other factors). For example, recent studies found O<sub>3</sub> to have little impact on white fir, but to greatly reduce growth of ponderosa pine in southern California locations, with associated reductions in ponderosa pine abundance in the community, and to cause decreased net primary production of most forest types in the mid-Atlantic region, with only small impacts on spruce-fir forest (U.S. EPA, 2013, section 9.4.3.4).

There is previously and newly available evidence of the potential for O<sub>3</sub> to alter biomass allocation and plant reproduction in seasons subsequent to exposure (U.S. EPA, 2013, section 9.4.3). For example, several studies published since the 2006 AQCD further demonstrate that O<sub>3</sub> can alter the timing of flowering and the number of flowers, fruits and seeds in herbaceous and woody plant species (U.S. EPA, 2013, section 9.4.3.3). Further, limited evidence in previous reviews reported that vegetation effects from a single year of exposure to elevated O<sub>3</sub> 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, 2013, 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<sub>3</sub> exposures in subsequent years.

A number of studies were conducted at a planted forest at the Aspen free-air carbon-dioxide and ozone enrichment (FACE) experiment 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<sub>3</sub>

concentrations. Some studies indicate the potential for carry-over effects, such as those showing that the effects of O<sub>3</sub> on birch seeds (reduced weight, germination, and starch levels) could lead to a negative impact on species regeneration in subsequent years, and that the O<sub>3</sub>-attributable effect of reduced aspen bud size might have been related to the observed delay in spring leaf development. These effects suggest that elevated O<sub>3</sub> 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, 2013, 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<sub>3</sub> 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<sub>3</sub> may alter intra- and inter-species competition within a forest stand (U.S. EPA, 2013, section 9.4.3; Kubiske *et al.*, 2006; Kubiske *et al.*, 2007). These studies confirm earlier FACE results of aspen growth reductions from exposure to elevated O<sub>3</sub> during the first seven years of stand growth and of cumulative biomass impacts associated with changes in annual production in studied tree communities (U.S. EPA, 2013, section 9.4.3; King *et al.*, 2005).

Robust and well-established E-R functions for RBL are available for 11 tree species: black cherry, Douglas fir, loblolly pine, ponderosa pine, quaking aspen, red alder, red maple, sugar maple, tulip poplar, Virginia pine, and white pine (U.S. EPA, 2013; U.S. EPA, 2014c). While these 11 species 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<sub>3</sub> (U.S. EPA, 2013, section 9.6.2; U.S. EPA, 2014b, section 6.2, Figure 6-2, Table 6-1). Supporting the E-R functions for each of these species are studies 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 (U.S. EPA, 2013, section 9.6.1). Based on these separate E-R functions, species-specific composite E-R functions have been

developed and successfully used to predict the biomass loss response from tree seedling species over a range of cumulative exposure conditions (U.S. EPA, 2013, section 9.6.2). These 11 composite functions, as well as the E-R function for eastern cottonwood (derived from a field study in which O<sub>3</sub> and climate conditions were not controlled),<sup>160</sup> 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, 2013, 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 (*e.g.*, 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 the WREA, summarized in section IV.C of the proposal, indicates the potential for within-species variability in these relationships for each species. Consideration of biomass loss estimates in the PA and in discussions below, however, is based on conventional methods and focuses on estimates for the 11 species for which the robust datasets from OTC experiments are available, in consideration of CASAC advice.

The “detrimental effect of O<sub>3</sub> on crop production has been recognized since the 1960s” (U.S. EPA, 2013, p. 1-10, section 9.4.4). On the whole, the newly available evidence supports and strengthens previous conclusions that exposure to O<sub>3</sub> reduces 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<sub>3</sub> exposure (U.S. EPA, 2013, section 9.4.4.1, Table 9-17). Studies have also “linked increasing O<sub>3</sub> concentration to decreased photosynthetic rates and accelerated aging in leaves, which are related to

yield” and described effects of O<sub>3</sub> 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, 2013, p. 1-10, section 9.4.4). The findings of the newly available studies do not change the basic understanding of O<sub>3</sub>-related crop yield loss since the last review and little additional information is available in this review on factors that influence associations between O<sub>3</sub> levels and crop yield loss (U.S. EPA, 2013, section 9.4.4.). However, the evidence available in this review continues to support the conclusion that O<sub>3</sub> in ambient air can reduce the yield of major commodity crops in the U.S. Further, the recent evidence increases our confidence in the use of crop E-R functions based on OTC experiments to characterize the quantitative relationship between ambient O<sub>3</sub> concentrations and yield loss (U.S. EPA, 2013, 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, as summarized in more detail in section IV.A of the proposal. The established E-R functions for relative yield loss (RYL)<sup>161</sup> were developed from OTC-type experiments from the National Crop Loss Assessment Network (NCLAN) (U.S. EPA, 2013, section 9.6.3; U.S. EPA, 2014b, section 6.2; U.S. EPA, 2014c, Figure 5-4 and section 6.3). With regard to the first area of uncertainty reduced, evaluations in the ISA found that yield loss in soybean from O<sub>3</sub> exposure at the SoyFACE (Soybean Free Air Concentration Enrichment) field experiment was reliably predicted by soybean E-R functions developed from NCLAN data (U.S. EPA, 2013, section 9.6.3.1),<sup>162</sup> demonstrating a robustness of the NCLAN-based E-R functions for predicting relative yield loss from O<sub>3</sub> exposure. A second area of uncertainty that was reduced is that regarding the

<sup>160</sup> The CASAC cautioned the EPA against placing too much emphasis on the eastern cottonwood data. In comments on the draft PA, the CASAC stated that the eastern cottonwood response data from a single study “receive too much emphasis,” 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, 2014c, p. 10).

<sup>161</sup> These functions for RYL estimate reduction in a year's growth as a percentage of that expected in the absence of O<sub>3</sub> (U.S. EPA, 2013, section 9.6.2; U.S. EPA, 2014b, section 6.2).

<sup>162</sup> The NCLAN program, which was undertaken in the early to mid-1980s, assessed multiple U.S. crops, locations, and O<sub>3</sub> exposure levels, using consistent methods, to provide the largest, most uniform database on the effects of O<sub>3</sub> on agricultural crop yields (U.S. EPA 1996a; U.S. EPA, 2006a; U.S. EPA, 2013, 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, 2013, section 9.2.4).

application of the NCLAN E-R functions 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<sub>3</sub> (U.S. EPA, 2006a; U.S. EPA, 2013, sections 9.6.3.1 and 9.6.3.4 and p. 9–59). The ISA comparisons of NCLAN and SoyFACE data referenced above also “confirm that the response of soybean yield to O<sub>3</sub> exposure has not changed in current cultivars” (U.S. EPA, 2013, p. 9–59; section 9.6.3.1). Additionally, a recent assessment of the relationship between soybean yield loss and O<sub>3</sub> in ambient air over the contiguous area of Illinois, Iowa, and Indiana found a relationship that correlates well with previous results from FACE- and OTC-type experiments (U.S. EPA, 2013, section 9.4.4.1).

### c. Biologically Relevant Exposure Metric

In assessing biologically based indices of exposure pertinent to O<sub>3</sub> effects on vegetation, the ISA states the following (U.S. EPA, 2013, p. 2–44).

The main conclusions from the 1996 and 2006 O<sub>3</sub> 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<sub>3</sub> concentrations appear to be more important than lower concentrations in eliciting a response; plant sensitivity to O<sub>3</sub> varies with time of day and plant development stage; [and] quantifying exposure with indices that cumulate hourly O<sub>3</sub> 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 includes a wealth of information on aspects of O<sub>3</sub> exposure that are important in influencing plant response (U.S. EPA, 1996a; U.S. EPA, 2006a; U.S. EPA, 2013). 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, 2013, 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<sub>3</sub> have been consistently well documented (U.S. EPA, 2013, section 9.5.3). Based on improved understanding of the biological basis for plant response to O<sub>3</sub> exposure, a large number of “mathematical approaches

for summarizing ambient air quality information in biologically meaningful forms for O<sub>3</sub> vegetation effects assessment purposes” have been developed (U.S. EPA, 2013, section 9.5.3), including those that cumulate exposures over some specified period while weighting higher concentrations more than lower (U.S. EPA, 2013, section 9.5.2). As with any summary statistic, these exposure indices retain information on some, but not all, characteristics of the original observations.

Based on extensive review of the published literature on different types of exposure-response metrics, including comparisons between metrics, the EPA has focused on cumulative, concentration-weighted indices, recognizing them as the most appropriate biologically based metrics to consider in this context (U.S. EPA, 1996a; U.S. EPA, 1996b; U.S. EPA, 2006a; U.S. EPA, 2013). In the last two reviews of the O<sub>3</sub> NAAQS, the EPA concluded that the risk to vegetation comes primarily from cumulative exposures to O<sub>3</sub> over a season or seasons<sup>163</sup> and focused on metrics intended to characterize such exposures: SUM06<sup>164</sup> in the 1997 review (61 FR 65716, December 13, 1996) and W126 in the 2008 review (72 FR 37818, July 11, 2007). Although in both reviews the policy decision was made not to revise the form and averaging time of the secondary standard, 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). This approach for characterizing O<sub>3</sub> 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).

Alternative methods for characterizing O<sub>3</sub> exposure to predict plant response have, in recent years,

<sup>163</sup> In describing the form as “seasonal,” the EPA is referring generally to the growing season of O<sub>3</sub>-sensitive vegetation, not to the seasons of the year (*i.e.*, spring, summer, fall, winter).

<sup>164</sup> The SUM06 index is a threshold-based approach described as the sum of all hourly O<sub>3</sub> concentrations greater or equal to 0.06 ppm observed during a specified daily and seasonal time window (U.S. EPA, 2013, section 9.5.2). The W126 index is a non-threshold approach, described more fully below.

included flux models, which some researchers have claimed may “better predict vegetation responses to O<sub>3</sub> than exposure-based approaches” because they estimate the ambient O<sub>3</sub> concentration that actually enters the leaf (*i.e.*, flux or deposition). However, the ISA notes that “[f]lux calculations are data intensive and must be carefully implemented” (U.S. EPA, 2013, p. 9–114). Further, the ISA states, “[t]his uptake-based approach to quantify the vegetation impact of O<sub>3</sub> requires inclusion of those factors that control the diurnal and seasonal O<sub>3</sub> flux to vegetation (*e.g.*, climate patterns, species and/or vegetation-type factors and site-specific factors)” (U.S. EPA, 2013, 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, 2013, 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<sub>3</sub> effects of concern based on the well-established conclusions and 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<sub>3</sub> exposures eliciting vegetation-related effects. Quantifying exposure in this way “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, 2013, section 2.6.6.1, p. 2–44). In this review, as in the last review, we use the W126-based cumulative, seasonal metric (U.S. EPA, 2013, 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.

This metric, commonly called the W126 index, is a non-threshold approach described as the sigmoidally weighted sum of all hourly O<sub>3</sub> concentrations observed during a specified daily and seasonal time window, where each hourly O<sub>3</sub> concentration is given a weight that increases from zero to one with increasing concentration (U.S. EPA, 2014c, p. 5–6; U.S. EPA 2013, p. 9–101).

The first step in calculating the seasonal W126 index, as described and considered in this review, is to sum the weighted ambient O<sub>3</sub> concentrations

during daylight hours (defined as 8:00 a.m. to 8:00 p.m.) within each calendar month, resulting in monthly index values (U.S. EPA, 2014b, pp. 4–5 to

4–6). As more completely described in the WREA, the monthly W126 index values are calculated from hourly O<sub>3</sub> concentrations as follows:

$$\text{Monthly W126} = \sum_{d=1}^N \sum_{h=8}^{19} \frac{C_{dh}}{1+4403 \cdot \exp(-126 \cdot C_{dh})}$$

where  $N$  is the number of days in the month,  $d$  is the day of the month ( $d = 1, 2, \dots, N$ ),  $h$  is the hour of the day ( $h = 0, 1, \dots, 23$ ), and  $C_{dh}$  is the hourly O<sub>3</sub> concentration observed on day  $d$ , hour  $h$ , in parts per million. The seasonal W126 index value for a specific year is the maximum sum of the monthly index values for three consecutive months. Three-year W126 index values are calculated by taking the average of seasonal W126 index values for three consecutive years (U.S. EPA, 2014b, pp. 4–5 to 4–6; Wells, 2014a).

## 2. Overview of Welfare Exposure and Risk Assessment

This section outlines the information presented in section IV.C of the proposal regarding the WREA conducted for this review, which built upon similar analyses performed in the last review. The WREA focuses primarily on analyses related to two types of effects on vegetation: Reduced growth (biomass loss) in both trees and agricultural crops, and foliar injury. The assessments of O<sub>3</sub>-associated reduced growth in native trees and crops (specifically, RBL and RYL, respectively) include analysis of associated changes in related ecosystem services, including pollution removal, carbon sequestration or storage, and hydrology, as well as economic impacts on the forestry and agriculture sectors of the economy. The foliar injury assessments include cumulative analyses of the proportion of USFS biosite index scores<sup>165</sup> above zero (or five, in a separate set of analyses) with increasing W126 exposure index estimates, with and without consideration of soil moisture conditions. The implications of visible foliar injury in national parks were considered in a screening level assessment and three case studies.<sup>166</sup>

<sup>165</sup> Sampling sites in the FIA/FHM O<sub>3</sub> biomonitoring program, called “biosites”, are plots of land on which data are collected regarding the incidence and severity of visible foliar injury on a variety of O<sub>3</sub>-sensitive plant species. Biosite index scores are derived from these data (U.S. EPA, 2014b, section 7.2.1).

<sup>166</sup> All of the analyses are described in detail in the WREA and summarized in the PA and in section IV.C of the proposal (U.S. EPA, 2014a; U.S.

Growth-related effects were assessed for W126-based exposure estimates in five scenarios of national-scale<sup>167</sup> air quality: Recent conditions (2006 to 2008), the existing secondary standard, and W126 index values of 15 ppm-hrs, 11 ppm-hrs, and 7 ppm-hrs, using 3-year averages (U.S. EPA, 2014b, chapter 4). For each of these scenarios, 3-year average W126 exposure index values were estimated for 12 kilometer (km) by 12 km grid cells in a national-scale spatial surface. The method for creating these grid cell estimates generally involved two steps (summarized in Table 5–4 of the PA).

The first step in creating the grid cell estimates for each scenario was calculation of the average W126 index value (across the three years) at each monitor location. For the recent conditions scenario, this value was based on unadjusted O<sub>3</sub> concentrations from monitoring data. For the other four scenarios, the W126 index value for each monitor location was calculated from model-adjusted hourly O<sub>3</sub> concentrations. The adjusted concentrations were based on model-predicted relationships between O<sub>3</sub> at each monitor location and reductions in NO<sub>x</sub>. Adjustments were applied independently for each of the nine U.S. regions (see U.S. EPA, 2014b, section 4.3.4.1).<sup>168</sup> The existing standard scenario was created first, with the result being a national dataset for which the highest monitor location in each U.S. region had a design value equal to the level of the current standard.<sup>169</sup> The W126 scenarios were created from the hourly concentrations used to create the existing standard scenario, with model-

EPA, 2014b; 79 FR 75324–75329, December 17, 2014).

<sup>167</sup> Although the scenarios and the grid cell O<sub>3</sub> concentrations on which they are based were limited to the contiguous U.S., we have generally used the phrase “national-scale” in reference to the WREA scenarios and surfaces.

<sup>168</sup> The U.S. regions referenced here and in section IV.C below are NOAA climate regions, as shown in Figure 2B–1 of the PA.

<sup>169</sup> The adjustment results in broad regional reductions in O<sub>3</sub> and includes reductions in O<sub>3</sub> at some monitors that were already at or below the target level. These reductions do not represent an optimized control scenario, but rather characterize one potential distribution of air quality across a region that meets the scenario target (U.S. EPA, 2014b, sections 4.3.4.2 and 4.4).

based adjustments made at all monitor sites in those regions with a site not already at or below the target W126 value for that scenario (U.S. EPA, 2014b, section 4.3.4.1).<sup>170</sup>

After completing step one for all the scenarios, the second step involved creating the national-scale spatial surfaces (composed of 3-year W126 index values at grid cell centroids). These were created by applying the Voronoi Neighbor Averaging (VNA) spatial interpolation technique to the monitor-location, 3-year W126 index values (described in step 1).<sup>171</sup> This step of creating the gridded spatial surfaces resulted in further reduction of the highest values in each modeling region, as demonstrated by comparing the W126 index values from steps one and two for the existing standard scenario. After the step-one adjustment of the monitor location concentrations such that the highest location in each NOAA region just met the existing standard (using relationships mentioned above), the maximum 3-year average W126 values in the nine regions 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). After application of the VNA technique in the second step, however, the highest 3-year average W126 values across the national surface grid cells, which were in the Southwest region, were below 15 ppm-hrs (U.S. EPA, 2014b, Figure 4–7).<sup>172</sup>

All of the assessments based on growth impacts relied on the W126 index estimates from the national-scale spatial surfaces (created from the 3-year average monitor location values as described above). Among the analyses related to visible foliar injury, a small component of the screening-level

<sup>170</sup> In regions where the air quality adjustment was applied, it was based on emissions reductions determined necessary for the highest monitor in that region to just equal the existing standard or the W126 target for the scenario. Concentrations at all other monitor locations in the region were also adjusted based on the same emissions reductions assumptions.

<sup>171</sup> The VNA technique is described in the WREA (U.S. EPA, 2014b, Appendix 4A).

<sup>172</sup> Thus, it can be seen that application of the VNA interpolation method to estimate W126 index values at the centroid of every 12 km x 12 km grid cell rather than only at each monitor location results in a lowering of the highest values in each region.

national park assessment and also the three national park case studies involved summarizing 3-year W126 index estimates from the four air quality scenarios. However, the visible foliar injury cumulative proportion analyses and a component of the national park screening-level assessment relied on national-scale spatial surfaces of single-year, unadjusted W126 index values created for each year from 2006 through 2010 using the VNA interpolation technique applied to the monitor location index values for these years (U.S. EPA, 2014b, section 4.3.2, Appendix 4A).

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 some components of the visible foliar injury assessments, limitations and uncertainties in the air quality analyses, which are discussed in detail in the WREA and some of which are mentioned here, are propagated into those analyses (U.S. EPA, 2014b, chapters 4 and 8 and section 8.5, Table 4–5). An important uncertainty in the analyses is the application of regionally determined emissions reductions to meet the existing standard (U.S. EPA, 2014b, section 8.5.1). The model adjustments are based on emissions reductions in NO<sub>x</sub> and characterize only one potential distribution of air quality across a region when all monitor locations meet the standard, as well as for the W126 scenarios (U.S. EPA, 2014b, section 4.3.4.2).<sup>173</sup>

An additional uncertainty related to the W126 index estimates in the national surfaces for each air quality scenario, and to the estimates for the single-year surfaces used in the visible foliar injury cumulative analysis, comes with the creation of the national-scale spatial surfaces of grid cells from the monitor-location O<sub>3</sub> data.<sup>174</sup> In general, spatial interpolation techniques perform better in areas where the O<sub>3</sub> monitoring network is denser. Therefore, the W126 index values estimated using this

<sup>173</sup> The adjustment is applied to all monitor locations in each region. In this way, the adjustment results in broad regional reductions in O<sub>3</sub> and includes reductions in O<sub>3</sub> 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.

<sup>174</sup> Some uncertainty is inherent in any approach to characterizing O<sub>3</sub> air quality over broad geographic areas based on concentrations at monitor locations.

technique in rural areas in the West, Northwest, Southwest, and West North Central regions where there are few or no monitors (U.S. EPA, 2014b, Figure 2–1) are more uncertain than those estimated for areas with denser monitoring. Further, as described above, this interpolation method generally underpredicts the highest W126 exposure index values. Due to the important influence of higher exposures in determining risks to plants, the potential for the VNA interpolation approach to dampen peak W126 index values could result in an underestimation of risks to vegetation in some areas.<sup>175</sup>

The vegetation analyses performed in the WREA, along with key observations, insights, uncertainties and limitations were summarized in sections IV.C.2 through IV.C.3 of the proposal. Highlights for the three categories of biomass loss and foliar injury assessments are summarized here.

#### a. Tree Growth, Productivity and Carbon Storage

These assessments rely on the species-specific E–R functions described in section IV.A.1.b above. For the air quality scenarios described above, the WREA applied the species-specific E–R functions to develop estimates of O<sub>3</sub>-associated RBL and associated effects on productivity, carbon storage and associated ecosystem services (U.S. EPA, 2014b, Chapter 6). More specifically, the WREA derived species-specific and weighted RBL estimates for grid cells across the continental U.S. and summarized the estimates by counties and national parks. Additional WREA case study analyses focused on selected urban areas. The WREA estimates indicate substantial heterogeneity in plant responses to O<sub>3</sub>, both within species (*e.g.*, study-specific variation), between species, and across regions of the U.S. National variability in the estimates (*e.g.*, eastern vs western U.S.) is influenced by there being different sets of resident species (with different E–R functions) in different areas of the U.S., as well as differences in number of national parks and O<sub>3</sub> monitors. For example, the eastern U.S. has different resident species compared to the western U.S., and the eastern U.S. has far more such species. Additionally, there are more national parks in the western than the eastern U.S., yet fewer O<sub>3</sub> monitors (U.S. EPA, 2014b, chapter 8).

<sup>175</sup> In the visible foliar injury dataset used for the cumulative analysis, underestimation of W126 index values at sites with injury would contribute to overestimates of the cumulative proportion of sites with injury plotted for the lower W126 values.

Relative biomass loss nationally (across all of the air quality surface grid cells) 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). In consideration of CASAC advice (summarized in section IV.A.1.b above), the WREA derived RBL and weighted RBL (wRBL) estimates separately, both with and without the eastern cottonwood, and the PA and proposal gave primary focus to analyses that exclude cottonwood. These analyses provided estimates of per-species and cross-species RBL in the different air quality scenarios. Air quality scenario estimates were also developed in terms of proportion of basal area affected at different magnitudes of RBL. The wRBL analysis integrated the species-specific estimates, providing an indication of potential magnitude of ecological effect possible in some ecosystems. The county analyses also included analyses focused on the median species response. The WREA also used the E–R functions to estimate RBL across tree lifespans and the resulting changes in consumer and producer/farmer economic surplus in the forestry and agriculture sectors of the economy. Case studies in five urban areas provided comparisons across air quality scenarios of estimates for urban tree pollutant removal and carbon storage or sequestration.

The array of uncertainties associated with estimates from these tree RBL analyses are summarized in the proposal and described in detail in the WREA, including the potential for the air quality scenarios to underestimate the higher W126 index values and associated implications for the RBL-related estimates, as referenced above.

#### b. Crop Yield Loss

These assessments rely on the species-specific E–R functions described in section IV.A.1.b above. For the different air quality scenarios, the WREA applied the species-specific E–R functions to develop estimates of O<sub>3</sub> impacts related to crop yield, including annual yield losses estimated for 10 commodity crops grown in the U.S. and how these losses affect producer and consumer economic surpluses (U.S. EPA, 2014b, sections 6.2, 6.5). The WREA derived estimates of crop RYL nationally and in a county-specific analysis, relying on information regarding crop distribution (U.S. EPA, 2014b, section 6.5). As with the tree analyses described above, the county analysis included estimates based on



the median O<sub>3</sub> response across the studied crop species (U.S. EPA, 2014b, section 6.5.1, Appendix 6B).

Overall effects on agricultural yields and producer and consumer surplus depend on the ability of producers/farmers to substitute other crops that are less O<sub>3</sub> sensitive, and the responsiveness, or elasticity, of demand and supply (U.S. EPA, 2014b, section 6.5). 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 Forest and Agriculture Sector Optimization Model (with greenhouse gases) at the estimated O<sub>3</sub> concentrations (U.S. EPA, 2014b, Table 6–27, section 8.5). Because the W126 index estimates generated in the air quality scenarios are inputs to the vegetation risk analyses for crop yield loss, any uncertainties in the air quality scenario estimation of W126 index values are propagated into 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).

### c. Visible Foliar Injury

The WREA presents a number of analyses of O<sub>3</sub>-related visible foliar injury and associated ecosystem services impacts (U.S. EPA, 2014b, Chapter 7). In the initial analysis, the WREA used the biomonitoring site data from the USFS FHM/FIA Network (USFS, 2011),<sup>176</sup> associated soil moisture data during the sample years, and national surfaces of ambient air O<sub>3</sub> concentrations based on spatial interpolation of monitoring data from 2006 to 2010 in a cumulative analysis of the proportion of biosite records with any visible foliar injury, as indicated by a nonzero biosite index score (U.S. EPA, 2014b, section 7.2). This analysis was done for all records together, and also for subsets based on soil moisture conditions (normal, wet or dry).

In each cumulative analysis, the biosite records were ordered by W126 index and then, moving from low to high W126 index, the records were cumulated into a progressively larger dataset. With the addition of each new

data point (composed of biosite index score and W126 index value for a biosite and year combination) to the cumulative dataset, the percentage of sites with a nonzero biosite index score was derived and plotted versus the W126 index estimate for the just added data point. The cumulative analysis for all sites indicates that (1) as the cumulative set of sites grows with addition of sites with progressively higher W126 index values, the proportion of the dataset for which no foliar injury was recorded changes (increases) noticeably prior to about 10 ppm-hrs (10.46 ppm-hrs), and (2) as the cumulative dataset grows still larger with the addition of records for higher W126 index estimates, the proportion of the cumulative dataset with no foliar injury remains relatively constant (U.S. EPA, 2014b, Figure 7–10). The data for normal moisture years are very similar to the dataset as a whole, with an overall proportion of about 18 percent for presence of any foliar injury. The data for relatively wet years have a much higher proportion of biosites showing injury, approximately 25% when all data are included, and a proportion of approximately 20% when data for W126 index estimates up to about 5–8 ppm-hrs are included (U.S. EPA, 2014b, Figure 7–10).<sup>177</sup> The overall proportion showing injury for the subset for relatively dry conditions is much lower, less than 15% for the subset (U.S. EPA, 2014b, section 7.2.3, Figures 7–10). 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 different exposure conditions is unclear from these analyses.

Criteria derived from the cumulative analyses were then used in two additional analyses. The national-scale screening-level assessment compared W126 index values estimated within 214 national parks using the VNA technique described above for the individual years from 2006 to 2010 with benchmark criteria developed from the biosite data analysis (U.S. EPA, 2014b, Appendix 7A and section 7.3). Separate case study analyses described visits, as well as visitor uses and expenditures for three national parks, and the 3-year

W126 index estimates in those parks for the four air quality scenarios (U.S. EPA, 2014b, section 7.4). Uncertainties associated with these analyses, included those associated with the W126 index estimates, 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).

### 3. Potential Impacts on 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 . . . 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)). The secondary standard is not meant to protect against all known or anticipated O<sub>3</sub>-related effects, but rather those that are judged to be adverse to the public welfare, and a bright-line determination of adversity is not required in judging what is requisite (78 FR 8312, January 15, 2013; see also 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<sub>3</sub> standards in past reviews.

As indicated by the Administrator in the 2008 decision, the degree to which O<sub>3</sub> 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 (73 FR 16496, March 27, 2008). Such judgments regarding public welfare significance in the last O<sub>3</sub> NAAQS decision gave particular consideration to O<sub>3</sub> effects in areas with special federal protections, and lands set aside by states, tribes and public interest groups to provide similar benefits to the public welfare (73 FR 16496, March 27, 2008). For example, in reaching his conclusion regarding the need for revision of the secondary standard in the 2008 review, the Administrator took

<sup>176</sup> Data were not available for several western states (Montana, Idaho, Wyoming, Nevada, Utah, Colorado, Arizona, New Mexico, Oklahoma, and portions of Texas).

<sup>177</sup> As discussed in section IV.C.2 below, as the cumulative set increases, with increasing W126 values, the overall prevalence of visible foliar injury in the cumulative set is more and more influenced by data for the lower W126 values. Accordingly, the “leveling off” observed above ~10 ppm-hrs in the ‘all sites’ analysis likely reflects the counterbalancing of visible foliar injury occurrence at the relatively fewer higher O<sub>3</sub> sites by the larger representation within the subset of the lower W126 conditions associated with which there is lower occurrence or extent of foliar injury.

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). As further recognized in the 2008 notice, “[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).<sup>178 179</sup> Such areas include Class I areas<sup>180</sup> which are federally mandated to preserve certain air quality related values. Additionally, as the Administrator recognized, “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<sub>3</sub>-sensitive species” (73 FR 16496, March 27, 2008).

The concept described in the 2008 notice regarding the degree to which effects on vegetation in specially protected areas, such as those identified above, may be judged adverse also applies beyond the species level to the ecosystem level, such that judgments

can depend on the intended use<sup>181</sup> for, or service (and value) of, the affected vegetation, ecological receptors, ecosystems and resources and the significance of that use to the public welfare (73 FR 16496, March 27, 2008). Uses or services provided by 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, at least in part, on the perceived scenic beauty of the environment (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)<sup>182</sup> were greater than those for recreation or other services (U.S. EPA, 2014b, Table 5–6; Haefele *et al.*, 1991; Holmes and Kramer, 1995).

The spatial, temporal and social dimensions of public welfare impacts are also influenced by the type of service affected. 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). Similarly, ecosystem services can be realized over a range of temporal scales. An evaluation of adversity to the public welfare might also consider the likelihood, type, and magnitude of the effect, as well as the potential for recovery and any uncertainties relating to these

conditions, as stated in the preamble of the 2012 final notice of rulemaking on the secondary standards for oxides of nitrogen and sulfur (77 FR 20232, April 3, 2012).

The three main categories of effects on vegetation discussed in section IV.A.1.b above 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 that describe 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, 2013, 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<sub>3</sub> 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, 2013, 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, and desired fire regimes (U.S. EPA 2013, 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 growth effects that might cause or contribute to adverse effects for trees, forests, forested ecosystems or the public welfare is complicated by aspects

<sup>178</sup> 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.

<sup>179</sup> 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).

<sup>180</sup> Areas designated as Class I 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. Other areas may also be Class I if designated as Class I consistent with the CAA.

<sup>181</sup> Ecosystem services have been defined as “the benefits that people obtain from ecosystems” (U.S. EPA, 2013, 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 the 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). Ecosystem services analyses were one of the tools used in the last review of the secondary standards for oxides of nitrogen and sulfur 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, April 3, 2012).

<sup>182</sup> Public surveys have indicated that Americans rank as very important the existence of resources, the option or availability of the resource and the ability to bequest or pass it on to future generations (Cordell *et al.*, 2008).

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 (described in section IV.A.1 above), provides no clear threshold or breakpoint in the response to O<sub>3</sub> exposure. Additionally, there are no established relationships between magnitude of tree seedling growth reduction and forest ecosystem impacts and, as noted in section IV.A.1.b above, other factors can influence the degree to which O<sub>3</sub>-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<sub>3</sub> sensitivity of the other co-occurring species (O<sub>3</sub> 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 estimates of impacts on tree seedling growth would indicate significance to the public welfare and thus be an important consideration in the level of protection for the secondary standard.

During the 1997 review of the secondary standard, views related to this issue were provided by a 1996 workshop of 16 leading scientists in the context of discussing their views for a secondary O<sub>3</sub> 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 (1–2% RBL and 5% or 10% RYL); nor does it describe their connection to ecosystem impacts of a specific

magnitude or type, nor to judgments on significance of the identified 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 is carbon storage, a regulating service that is “of paramount importance for human society” (U.S. EPA, 2013, section 2.6.2.1 and p. 9–37). As noted above, the EPA has concluded that this ecosystem service has a likely causal relationship with O<sub>3</sub> in ambient air. 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<sub>3</sub>-related impacts but not necessarily identified for such protection might be forested lands, both public and private, where trees are grown for timber production. Forests in urbanized areas also provide a number of services that are important to the public in those areas, such as air pollution removal, cooling, and beautification. There are also many other tree species, such as species identified by the USFS and various ornamental and agricultural species (*e.g.*, Christmas trees, fruit and nut trees), that provide ecosystem services that may be judged important to the public welfare but whose vulnerability to O<sub>3</sub> impacts has not been quantitatively characterized (U.S. EPA, 2014b, Chapter 6).

As noted above, in addition to tree growth-related effects, O<sub>3</sub>-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<sub>3</sub> 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<sub>3</sub>-induced foliar injury (USFS, NPS, FWS, 2010). An AQRV is defined by the National Park Service as a “resource, as identified by the [federal land manager] 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 [federal land manager] for a particular area” (USFS, NPS, USFWS, 2010).<sup>183</sup> 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.A.1.b above, there is not a clear relationship between visible foliar injury and other effects, such as reduced growth and productivity.<sup>184</sup> Thus, key considerations with regard to public welfare significance of this endpoint

<sup>183</sup> 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 in Class I areas from pending permit actions (USFS, NPS, USFWS, 2010). An adverse impact is recognized by the National Park Service as one that results in diminishment of the Class I area’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 make such adverse impact determinations on a case-by-case basis, using technical and other information that they provide for consideration by permitting authorities. The National Park Service has developed 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](http://www.nature.nps.gov/air/Pubs/pdf/AQGuidance_2011-01-14.pdf)).

<sup>184</sup> The National Park Service identifies various ranges of W126 index values in providing approaches for assessing air quality-related impacts of various development projects which appear to be based on the 1996 workshop report (Heck and Cowling, 1997), and may, at the low end, relate to a benchmark derived for the highly sensitive species, black cherry, for growth effects (10% RBL), rather than visible foliar injury (Kohut, 2007; Lefohn *et al.*, 1997). As noted in section IV.A.1.b above, visible foliar injury is not always a reliable indicator of other negative effects on vegetation (U.S. EPA, 2013, p. 9–39). We also note that the USFS biomonitoring analyses of visible foliar injury biomonitoring data commonly make use of a set of biosite index categories for which risk assumptions have been assigned, providing a relative scale of possible impacts (Campbell *et al.*, 2007); however, little information is available on the studies, effects and judgments on which these categories are based.

have related to qualitative consideration of the plant's aesthetic value in protected forested areas. Depending on the extent and severity, O<sub>3</sub>-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<sub>3</sub>-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<sub>3</sub> 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<sub>3</sub> is potentially appreciable. Sixty-six plant species that occur on U.S. National Park Service (NPS) and U.S. Fish and Wildlife Service lands<sup>185</sup> have been identified as sensitive to O<sub>3</sub>-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<sub>3</sub>, however, and quantitative E–R relationships for O<sub>3</sub> exposure and other important effects, such as seedling growth reduction, are only available for a subset of 12 of the 66, as summarized in section IV.A.1.b above. A diverse array of ecosystem services has been identified for these twelve species (U.S. EPA, 2014c, Table 5–1). Two species in this group that are slightly more sensitive than the median for the group 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<sub>3</sub> concentrations and associated cumulative seasonal exposures can be highest (U.S. EPA, 2014c, Appendix 2B).<sup>186</sup>

With regard to agriculture-related effects, the EPA has recognized other complexities, stating that the degree to

which O<sub>3</sub> 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). As noted in section IV.B.2 of the proposal, while having sufficient crop yields is of high public welfare value, important commodity crops are typically heavily managed to produce optimum 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. These competing impacts on producers and consumers complicate consideration of 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<sub>3</sub>-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 (FR 73 16496–16497, March 27, 2008).

In summary, several considerations are recognized as important to judgments on the public welfare significance of the array of effects of different O<sub>3</sub> 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<sub>3</sub>-sensitive tree species are present that may be vulnerable to impacts from O<sub>3</sub> on tree growth, productivity and carbon storage and their associated ecosystems and services. Cumulative exposures that may elicit effects and the significance of the effects in specific situations can vary due to differences in exposed species sensitivity, the importance of the observed or predicted O<sub>3</sub>-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.

#### *B. Need for Revision of the Secondary Standard*

The initial issue to be addressed in this review of the secondary standard for O<sub>3</sub> is whether, in view of the currently available scientific evidence, exposure and risk information and air quality analyses, as reflected in the record, the standard should be retained or revised. In drawing conclusions on adequacy of the current O<sub>3</sub> secondary standard, the Administrator has taken into account both evidence-based and quantitative exposure- and risk-based considerations, as well as advice from CASAC and public comment. 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<sub>3</sub> 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 the EPA assessments of risk of key welfare effects, including O<sub>3</sub> 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.

In evaluating whether it is appropriate to revise the current standard, the Administrator's considerations build on the general approach used in the last review, as summarized in section IV.A of the proposal, and reflect the body of evidence and information available during this review. The approach used is based on an integration of the information on vegetation effects associated with exposure to O<sub>3</sub> in ambient air, as well as policy judgments on the adversity of such effects to public welfare and on when the standard is requisite to protect public welfare from known or anticipated adverse effects. Such judgments are informed by air quality and related analyses, quantitative assessments, when available, and qualitative assessment of impacts that could not be quantified. The Administrator has taken into

<sup>185</sup> See <http://www2.nature.nps.gov/air/Pubs/pdf/flag/NPSzonesensppFLAG06.pdf>.

<sup>186</sup> 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>. Basal area is generally described as the area of ground covered by trees.

account both evidence of effects on vegetation and ecosystems and public uses of these entities that may be important to the public welfare. The decision on adequacy of the protection provided by the current standard has also considered the 2013 remand of the secondary standard by the D.C. Circuit such that this decision incorporates the EPA's response to this remand.

Section IV.B.1 below summarizes the basis for the proposed decision by the Administrator that the current secondary standard should be revised. Significant comments received from the public on the proposal are discussed in section IV.B.2 and the Administrator's final decision is described in section IV.B.3.

#### 1. Basis for Proposed Decision

In evaluating whether it was appropriate to propose to retain or revise the current standard, as discussed in section IV.D of the proposal, the Administrator carefully 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 that had been offered up to that point. In the paragraphs below, we summarize the proposal presentation of the PA considerations with regard to adequacy of the current secondary standard, advice from the CASAC, and the Administrator's proposed conclusions, drawing from section IV.D of the proposal, where a fuller discussion is presented.

##### a. Considerations and Conclusions in the PA

The PA evaluation is based on the longstanding evidence for O<sub>3</sub> effects and the associated conclusions in the current review of causal and likely causal relationships between O<sub>3</sub> in ambient air and an array of welfare effects at a range of biological and ecological scales of organization, as summarized in section IV.A.1 above (and described in detail in the ISA). Drawing from the ISA and CASAC advice, the PA emphasizes the strong support in the evidence for the conclusion that effects on vegetation are attributable to cumulative seasonal O<sub>3</sub> exposures, taking note of the improved "explanatory power" (for effects on vegetation) of the W126 index over other exposure metrics, as summarized in section IV.A.1.c above. The PA further recognizes the strong basis in the evidence for the conclusion that it is appropriate to use a cumulative

seasonal exposure metric, such as the W126 index, to judge impacts of O<sub>3</sub> on vegetation; related effects on ecosystems and services, such as carbon storage; and the level of public welfare protection achieved for such effects (U.S. EPA, 2014c, p. 5–78). As a result, based on the strong support in the evidence and advice from CASAC in the current and past reviews, the PA concludes that the most appropriate and biologically relevant way to relate O<sub>3</sub> exposure to plant growth, and to determine what would be adequate protection for public welfare effects attributable to the presence of O<sub>3</sub> in ambient air, is to characterize exposures in terms of a cumulative seasonal form, and in particular the W126 metric (U.S. EPA, 2014c, pp. 5–7 and 5–78). Accordingly, in considering the evidence with regard to level of protection provided by the current secondary standard, the PA considers air quality data and exposure-response relationships for vegetation effects, particularly those related to forest tree growth, productivity and carbon storage, in terms of the W126 index (U.S. EPA, 2014c, section 5.2; 79 FR 75330–75333, December 17, 2014).

In considering the extent to which such growth-related effects might be expected to occur under conditions that meet the current secondary standard, the PA focused particularly on tree seedling RBL estimates for the 11 species for which robust E–R functions have been developed, noting the CASAC concurrence with use of O<sub>3</sub>-related tree biomass loss as a surrogate for related effects extending to the ecosystem scale (U.S. EPA, 2014c, p. 5–80, Frey, 2014c, p. 10). The PA evaluation relied on RBL estimates for these 11 species derived using the robust 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, 2013, section 9.6.3.2).

In considering the RBL estimates for different O<sub>3</sub> conditions associated with the current standard, the PA focused primarily on the median of the species-specific (composite) E–R functions. In so doing, in the context of considering the adequacy of protection afforded by the current standard, the PA takes note of CASAC's view regarding a 6% median RBL (Frey, 2014c, p. 12). Based on the summary of RBL estimates in the PA, the PA notes that the median species RBL estimate, across the 11 estimates derived from the robust species-specific E–R functions, is at or above 6% for W126 index values of 19

ppm-hrs and higher (U.S. EPA, 2014c, Tables 6–1 and 5C–3).

In recognition of the potential significance to public welfare of vegetation effects in Class I areas, the proposal described in detail findings of the PA analysis of the occurrence of O<sub>3</sub> concentrations associated with the potential for RBL estimates above benchmarks of interest in Class I areas that meet the current standard, focusing on 22 Class I areas for which air quality data indicated the current standard was met and cumulative seasonal exposures, in terms of a 3-year average W126 index, were at or above 15 ppm-hrs (79 FR 75331–75332, Table 7, December 17, 2014; U.S. EPA, 2014c, Table 5–2). The PA noted that W126 index values (both annual and 3-year average values) in many such areas, distributed across multiple states and NOAA climatic regions, were above 19 ppm-hrs. The highest 3-year average value was over 22 ppm-hrs and the highest annual value was over 27 ppm-hrs, exposure values for which the corresponding median species RBL estimates markedly exceed 6%, which CASAC has termed "unacceptably high" (U.S. EPA, 2014c, section 5.2). The PA additionally considered the species-specific RBL estimates for two tree species (quaking aspen and ponderosa pine) that are found in many of these Class I areas and that have a sensitivity to O<sub>3</sub> exposure that places them slightly more sensitive than the median of the group for which robust E–R functions have been established (U.S. EPA, 2014c, sections 5.2 and 5.7). As further summarized in the proposal, the PA describes the results of this analysis, particularly in light of advice from CASAC regarding the significance of the 6% RBL benchmark, as evidence of the occurrence in Class I areas, during periods when the current standard is met, of cumulative seasonal O<sub>3</sub> exposures of a magnitude for which the tree growth impacts indicated by the associated RBL estimates might reasonably be concluded to be important to public welfare (79 FR 75332; U.S. EPA, 2014c, sections 5.2.1 and 5.7).

The proposal also noted that the PA additionally considered findings of the WREA analyses of O<sub>3</sub> effects on tree growth and an array of ecosystem services provided by forests, including timber production, carbon storage and air pollution removal (79 FR 75332–75333; U.S. EPA, 2014b, sections 6.2–6.8; U.S. EPA, 2014c, section 5.2). While recognizing that these analyses provide quantitative estimates of impacts on tree growth and associated services for several different air quality scenarios,

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 recognizes significant uncertainties associated with the absolute magnitude of the estimates for these ecosystem service endpoints which limited the weight placed on these results (U.S. EPA, 2014c, sections 5.2 and 5.7).

As described in the proposal, the PA also considered O<sub>3</sub> effects on crops, taking note of the extensive and long-standing evidence of the detrimental effect of O<sub>3</sub> on crop production, which continues to be confirmed by evidence newly available in this review (79 FR 75333; U.S. 2014c, sections 5.3 and 5.7). With regard to consideration of the quantitative impacts of O<sub>3</sub> exposures under exposure conditions associated with the current standard, the PA focused on RYL estimates that had strong support in the current evidence (as characterized in the ISA, section 9.6) in light of CASAC comments regarding RYL benchmarks (Frey, 2014c, pp. iii and 14). In considering such evidence-based analyses, as well as the exposure/risk-based information for crops, the PA notes the CASAC comments regarding the use of crop yields as a surrogate for consideration of public welfare impacts, which noted that “[c]rops provide food and fiber services to humans” and that “[e]valuation of market-based welfare effects of O<sub>3</sub> 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.A.3 above that the determination of the point at which O<sub>3</sub>-induced crop yield loss becomes adverse to the public welfare is still unclear, given that crops are heavily managed (*e.g.*, with fertilizer, irrigation) for optimum yields, have their own associated markets and that benefits can be unevenly distributed between producers and consumers (79 FR 75322; U.S. EPA, 2014c, sections 5.3 and 5.7).

With regard to visible foliar injury, as summarized in the proposal, the PA recognizes the long-standing evidence that has established that O<sub>3</sub> causes diagnostic visible foliar injury symptoms on studied bioindicator

species and also recognizes that such O<sub>3</sub>-induced impacts have the potential to impact the public welfare in scenic and/or recreational areas, with visible foliar injury 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<sub>3</sub>-sensitive species (including bioindicator species) are culturally significant (U.S. EPA, 2014c, Table 5–1). Similarly, the PA 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). Given the above, and taking note of CASAC views, the PA recognizes visible foliar injury as an important O<sub>3</sub> 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, such as national parks and other Class I areas.

As summarized in the proposal, the PA additionally takes note of the evidence described in the ISA regarding the role of soil moisture conditions that can decrease the incidence and severity of visible foliar injury under dry conditions (U.S. EPA, 2014c, sections 5.4 and 5.7). 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 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). 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<sub>3</sub>-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 for greater protection. In so doing, however, the PA recognizes that

the degree to which O<sub>3</sub>-induced visible foliar injury would be judged important and potentially adverse to public welfare is uncertain (U.S. EPA, 2014c, section 5.7).

As noted in the proposal, with regard to other welfare effects, for which the ISA determined a causal or likely causal relationships with O<sub>3</sub> in ambient air, such as alteration of ecosystem water cycling and changes in climate, the PA concludes there are limitations in the available information that affect our ability to consider potential impacts of air quality conditions associated with the current standard.

Based on the considerations described in the PA, summarized in the proposal and outlined 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 provide support for considering potential alternative standards to provide 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<sub>3</sub> exposures associated with estimates of tree growth impacts of a magnitude that may reasonably be considered important to public welfare.

#### b. CASAC Advice

The proposal also summarized advice offered by the CASAC in the current review, based on the updated scientific and technical record since the 2008 rulemaking. The CASAC stated that it “[supports] 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 CASAC further stated “[w]e support the 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 “concur[red] 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, and 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 (8 a.m.–8 p.m.) over the 3-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,” listing an array of related ecosystem services (Frey, 2014c, p. 10). With respect to RBL for tree species, CASAC states that it is appropriate to identify in the PA “a range of levels of alternative W126-based standards that 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” (Frey, 2014c, pp. 13 and 14). 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” and described crop yield as a surrogate for related services (Frey, 2014c, p. 13).

### c. Administrator’s Proposed Conclusions

At the time of proposal, the Administrator took into account the information available in the current review with regard to the nature of O<sub>3</sub>-related effects on vegetation and the adequacy of protection provided by the current secondary standard. The Administrator recognized the appropriateness and usefulness of the W126 metric in evaluating O<sub>3</sub> exposures of potential concern for vegetation effects, additionally noting support conveyed by CASAC for such a use for this metric. Further, the Administrator took particular note of (1) 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; (2) the monitoring analysis in the PA of cumulative exposures (in terms of W126 index) occurring in locations where the current standard is met, including those locations in or near Class I areas, and associated estimates of tree seedling growth effects; and (3) the analyses in the WREA illustrating the geographic distribution of tree species for which E–R functions are available and estimates of O<sub>3</sub>-related growth impacts for

different air quality scenarios, taking into account the identified potential for the WREA’s existing standard scenario to underestimate the highest W126-based O<sub>3</sub> values that would be expected to occur.

With regard to considering the adequacy of public welfare protection provided by the current secondary standard at the time of proposal, the Administrator focused first on welfare effects related to reduced native plant growth and productivity in terrestrial systems, taking note of the following: (a) The ISA conclusion of a causal relationship between O<sub>3</sub> in the ambient air and these welfare effects, and supporting evidence related to O<sub>3</sub> effects on vegetation growth and productivity, including the evidence from OTC studies of tree seedling growth that support robust E–R functions for 11 species; (b) the evidence, described in section IV.D.1 of the proposal and summarized above, of the occurrence of cumulative seasonal O<sub>3</sub> exposures for which median species RBL estimates are of a magnitude that CASAC has termed “unacceptably high” in Class I areas during periods where the current standard is met; (c) 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 as national parks and forests, wildlife refuges, and wilderness areas (many of which have been designated Class I areas); and (d) PA conclusions that the current information calls into question the adequacy of the current standard, based particularly on impacts on tree growth (and the potential for associated ecosystem effects), estimated for Class I area conditions meeting the current standard, that 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.

At the time of proposal, the Administrator also recognized the causal relationships between O<sub>3</sub> 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, she took 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, and she

additionally recognized 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 recognized the complexity of considering adverse O<sub>3</sub> impacts to public welfare due to the heavy management common for achieving optimum yields and market factors that influence associated services and additionally took 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 proposed to conclude that the current standard is not requisite to protect public welfare from known or anticipated adverse effects and that revision is needed to provide the requisite 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 concluded 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<sub>3</sub> secondary standard. She further noted 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 of the proposal, as well as other welfare effects of O<sub>3</sub>, including visible foliar injury and crop yield loss.

### 2. Comments on the Need for Revision

In considering comments on the need for revision, we first note the advice and recommendations from CASAC with regard to the adequacy of the current standard. In its review of the second draft PA, CASAC stated that it “supports the scientific 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).

General comments received from the public on the proposal that are based on relevant factors and either supported or opposed the proposed decision to revise



the current O<sub>3</sub> secondary standard are addressed in this section. Comments on specific issues or information that relate to consideration of the appropriate elements of a revised secondary standard are addressed below in section IV.C. Other specific comments related to standard setting, as well as general comments based on implementation-related factors that are not a permissible basis for considering the need to revise the current standard, are addressed in the Response to Comments document.

Public comments on the proposal were divided with regard to support for the Administrator's proposed decision to revise the current secondary standard. Many state and local environmental agencies or government bodies, tribal agencies and organizations, and environmental organizations agreed with the EPA's proposed conclusion on the need to revise the current standard, stating that the available scientific information shows that O<sub>3</sub>-induced vegetation and ecosystem effects are occurring under air quality conditions allowed by the current standard and, therefore, provides a strong basis and support for the conclusion that the current secondary standard is not adequate. In support of their view, these commenters relied on the entire body of evidence available for consideration in this review, including evidence assessed previously in the 2008 review. These commenters variously pointed to the information and analyses in the PA and the conclusions and recommendations of CASAC as providing a clear basis for concluding that the current standard does not provide adequate protection of public welfare from O<sub>3</sub>-related effects. Many of these commenters generally noted their agreement with the rationale provided in the proposal with regard to the Administrator's proposed conclusion on adequacy of the current standard, and some gave additional emphasis to several aspects of that rationale, including the appropriateness of the EPA's attention to sensitive vegetation and ecosystems in Class I areas and other public lands that provide similar public welfare benefits and of the EPA's reliance on the strong evidence of impacts to tree growth and growth-related effects.

Comments from tribal organizations additionally noted that many Class I areas are of sacred value to tribes or provide treaty-protected benefits to tribes, including the exercise of gathering rights. Tribal organizations also noted the presence in Class I areas of large numbers of culturally important plant species, which they indicate to be impacted by air quality conditions

allowed by the current standard. The impacts described include visible foliar injury, loss in forest growth and crop yield loss, which these groups describe as especially concerning when occurring on lands set aside for the benefit of the public or that are of sacred value to tribes or provide treaty-protected benefits to tribes.

As described in section IV.B.3 below, the EPA generally agrees with the view of these commenters regarding the need for revision of the current secondary standard and with CASAC that the evidence provides support for the conclusions that the current secondary standard is not adequate to protect public welfare from known or anticipated adverse effects, particularly with respect to effects on vegetation.

A number of industries, industry associations, or industry consultants, as well as some state governors, attorneys general and environmental agencies, disagreed with the EPA's proposed conclusion on the adequacy of the current standard and recommended against revision. In support of their position, these commenters variously stated that the available evidence is little changed from that available at the time of the 2008 decision, and that the evidence is too uncertain, including with regard to growth-related effects and visible foliar injury, to support revision, and does not demonstrate adverse effects to public welfare for conditions associated with the current standard, with some commenters stating particularly that the EPA analysis of Class I areas did not document adverse effects to public welfare. They also cited the WREA modeling analyses as indicating that any welfare improvements associated with a revised standard would be marginal; in particular, compared to the benefits of achieving the current standard. Further, they state that, because of long-range transport of O<sub>3</sub> and precursors, it is not appropriate for the EPA to draw conclusions about the level of protection offered by the current standard based on current air quality conditions; in support of this view, these commenters point to different modeling analyses as demonstrating that under conditions where the current standard is met throughout the U.S., the associated W126 values would all be below the upper end of the range proposed as providing requisite public welfare protection and nearly all below the lower end of 13 ppm-hrs.

As an initial matter, we note that, as noted in sections I.C and IV.A above, the EPA's 2008 decision on the secondary standard was remanded back to the Agency because in setting the

2008 secondary standard, the EPA failed to specify what level of air quality was requisite to protect public welfare from known or anticipated adverse effects or explain why any such level would be requisite. So, in addressing the court remand, the EPA has more explicitly considered the extent to which protection is provided from known or anticipated effects that the Administrator may judge to be adverse to public welfare, and has described how the air quality associated with the revised standard would provide requisite public welfare protection, consistent with CAA section 109(b)(2) and the court's decision remanding the 2008 secondary standard. In undertaking this review, consistent with the direction of the CAA, the EPA has considered the current air quality criteria.

While we recognize, as stated in the proposal, that the evidence newly available in this review is largely consistent with the evidence available at the time of the last review (completed in 2008) with regard to the welfare effects of O<sub>3</sub>, we disagree with the commenters' interpretations of the evidence and analyses available in this review and with their views on the associated uncertainties. As summarized in section IV.A above, the ISA has determined causal relationships to exist between several vegetation and ecosystem endpoints and O<sub>3</sub> in ambient air (U.S. 2013, section 9.7). The ISA characterized the newly available evidence as largely consistent with and supportive of prior conclusions, as summarized in section IV.A above. This is not to say, however, that there is no newly available evidence and information in this review or that it is identical to that available in the last review. In some respects, the newly available evidence has strengthened the evidence available in the last review and reduced important uncertainties. As summarized in section IV.A.1.b above, newly available field studies confirm the cumulative effects and effects on forest community composition over multiple seasons. Additionally, among the newly available evidence for this review are analyses documented in the ISA that evaluate the RBL and RYL E-R functions for aspen and soybean, respectively, with experimental datasets that were not used in the derivation of the functions (U.S. 2013, section 9.6.3). These evaluations confirm the pertinence of the tree seedling RBL estimates for aspen, a species with sensitivity roughly midway in the range of sensitivities for the studied species, across multiple years in older trees.

With regard to crops, the ISA evaluations demonstrate a robustness of the E-R functions to predict O<sub>3</sub>-attributable RYL and confirm the relevance of the crop RYL estimates for more recent cultivars currently growing in the field. Together, the information newly available in this review confirms the basis for the E-R functions and strengthens our confidence in interpretations drawn from their use in other analyses newly available in this review that have been described in the WREA and PA.

With regard to comments on uncertainties associated with estimates of RBL, we first note that these established, robust E-R functions, which the EPA gave particular emphasis in this review, are available for seedling growth for 11 tree species native to the U.S., as summarized in section IV.A.1.b above and described in the proposal. These E-R functions are based on studies of multiple genotypes of 11 tree species grown for up to three years in multiple locations across the U.S. (U.S. EPA, 2013, section 9.6.1). We have recognized the uncertainty regarding the extent to which the studied species encompass the O<sub>3</sub> sensitive species in the U.S. and also the extent to which they represent U.S. vegetation as a whole (U.S. EPA, 2014b, section 6.9). However, the studied species include both deciduous and coniferous trees with a wide range of sensitivities and species native to every region across the U.S. and in most cases are resident across multiple states and NOAA climatic regions (U.S. EPA, 2014b, Appendix 6A). While the CASAC stated that there is “considerable uncertainty in extrapolating from the [studied] forest tree species to all forest tree species in the U.S.,” it additionally expressed the view that it should be anticipated that there are highly sensitive vegetation species for which we do not have E-R functions and others that are insensitive.<sup>187</sup> In so doing, the CASAC stated that it “should not be assumed that species of unknown sensitivity are tolerant to ozone” and “[i]t is more appropriate to assume that the sensitivity of species without E-R functions might be similar to the range of sensitivity for those species with E-R functions” (Frey, 2014c, p. 11). Accordingly, we disagree with commenters’ view that effects on these species are not appropriate

<sup>187</sup> Use of RBL estimates in the proposal, and in this final decision, focuses on the RBL for the studied species as a surrogate for a broad array of growth-related effects of potential public welfare significance, consistent with the CASAC advice.

considerations for evaluation of the adequacy of the current standard.

In support of their view that RBL estimates are too uncertain to inform a conclusion that the current standard is not adequately protective of public welfare, some commenters state that some of the 11 E-R functions are based on as few as one study. The EPA agrees that there are two species for which there is only one study supporting the E-R function (Virginia pine and red maple). We also note, however, that those two species are appreciably less sensitive than the median (Lee and Hogsett, 1996; U.S. EPA, 2014c, Table 5C-1). Thus, in the relevant analyses, they tend to influence the median toward a relatively less (rather than more) sensitive response. Further, there are four species for which the E-R functions are based on more than five studies,<sup>188</sup> contrary to the commenters’ claims of there being no functions supported by that many studies. That said, the EPA has noted the relatively greater uncertainty in the species for which fewer studies are available, and it is in consideration of such uncertainties that the EPA focused in the proposal on the median E-R function across the 11 species, rather than a function for a species much more (or less) sensitive than the median. The EPA additionally notes that it gave less emphasis to the E-R function available for one species, eastern cottonwood, based on CASAC advice that the study results supporting that E-R function were not as strong as the results of the other experiments that support the other, robust E-R functions and that the eastern cottonwood study results showed extreme sensitivity to O<sub>3</sub> compared to other studies (Frey, 2014c, p. 10). Accordingly, the EPA has appropriately considered the strength of the scientific evidence and the associated uncertainties in considering revision of the secondary standard.

Other commenters stated that the scientific evidence does not support revising the NAAQS, pointing to uncertainty related to interpretation of the RBL estimates (based on tree seedling studies) with regard to effects on older tree lifestages. Some of these commenters’ claim that mature canopy trees experience reduced O<sub>3</sub> effects. The EPA agrees that the quantitative information for O<sub>3</sub> growth effects on older tree lifestages is available for a more limited set of species than that available for tree seedlings. We note,

<sup>188</sup> These four species, aspen, Douglas fir, ponderosa pine and red alder, range broadly in sensitivities that fall above, below and at the median for the 11 species (Lee and Hogsett, 1996; U.S. EPA, 2014c, Table 5C-1).

however, that this is an area for which there is information newly available in this review. A detailed analysis of study data for seedlings and older lifestages of aspen shows close agreement between the O<sub>3</sub>-attributable reduced growth observed in the older trees and reductions predicted from the seedling E-R function (U.S. EPA, 2013, section 9.6.3.2; discussed in the PA, section 5.2.1 as noted in the proposal, p. 75330). This finding, newly available in this review and documenting impacts on mature trees, improves our confidence in conclusions drawn with regard to the significance of RBL estimates for this species, which is prevalent across multiple regions of the U.S.<sup>189</sup> It is also noteworthy that this species is generally more sensitive to O<sub>3</sub> effects on growth than the median of the 11 species with robust E-R functions (as shown in U.S. EPA 2014c, Table 5C-1). Other newly available studies, summarized in section IV.A.1.b above and section IV.B.1.b of the proposal, provide additional evidence of O<sub>3</sub> impacts on mature trees, including a meta-analysis reporting older trees to be more affected by O<sub>3</sub> than younger trees (U.S. EPA, 2013, p. 9-42; Wittig et al., 2007). We additionally note that CASAC “concur[red] 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” additionally stating that “[b]iomass loss may also have indirect process-related effects such as on nutrient and hydrologic cycles” leading them to conclude that “[t]herefore, biomass loss is a scientifically valid surrogate of a variety of adverse effects to public welfare” (Frey, 2014c, p. 10).

As noted in section IV.A above and discussed below, the Administrator’s final decision on the adequacy of the current standard draws upon, among other things, the available evidence and quantitative analyses as well as judgments about the appropriate weight to place on the range of uncertainties inherent in the evidence and analyses. The strengthening in this review, as compared with the last review, of the basis for the robust E-R functions for tree seedling RBL, as well as other newly available quantitative analyses,

<sup>189</sup> The WREA notes a few additional, limited analyses using modeling tools and data from previous publications that indicate there may be species-specific differences in the extent of similarities between seedling and adult growth response to O<sub>3</sub>, with some species showing greater and some lesser response for seedlings as compared to mature tree, but a general comparability (U.S. EPA 2014b, section 6.2.1.1 and p. 6-67).

will, accordingly, contribute to judgments made by the Administrator with regard to these effects in reaching her final decisions in this review.

Amongst the newly available information in this review is a new analysis describing W126-based exposures occurring in counties containing Class I areas for which monitoring data indicated compliance with the current standard. The PA gave particular attention to this analysis in consideration of the adequacy of the current standard, and this analysis was also described in the proposal (U.S. EPA, 2014c, Appendix 5B and pp. 5–27 to 5–29; 79 FR 75331–75332, December 17, 2014). Some of the commenters who disagreed with the EPA’s conclusion on adequacy of the current standard variously stated that this analysis does not demonstrate growth effects are occurring in Class I areas and that the analysis is too uncertain for reliance on by the Administrator in her judgment on adequacy of the current standard. While the EPA agrees with commenters that data on the occurrence of growth effects in the areas and time periods identified are not part of this analysis, we note that this is because such data have not been collected and consequently cannot be included. As a result, the EPA has utilized measurements of O<sub>3</sub> in or near these areas in combination with the established E–R functions to estimate the potential for growth impacts in these areas under conditions where the current standard is met. The EPA additionally notes that species for which E–R functions have been developed have been documented to occur within these areas (see Table 3).

The EPA disagrees with commenters regarding the appropriateness of this analysis for the Administrator’s consideration. This analysis documents the occurrence of cumulative growing

season exposures in these ecosystems which the EPA and CASAC have interpreted, through the use of the established E–R functions for tree seedling growth effects summarized in section IV.A.1.b above (and described in the ISA, PA and proposal), as indicating the potential for growth effects of significance in these protected areas. To the extent that these comments imply that the Administrator may only consider welfare effects that are certain in judging the adequacy of the current standard, we note that section 109(b)(2) of the CAA plainly provides for consideration of both known and anticipated adverse effects in establishing or revising secondary NAAQS.

In support of some commenters’ view that this analysis is too uncertain to provide a basis for the Administrator’s proposed conclusion that the current standard is not adequate, one commenter observed that the O<sub>3</sub> monitors used for six of the 22 Class I areas in the analysis, although in the same county, were sited outside of the Class I areas. This was the case due to the analysis being focused on the highest monitor in the county that met the current standard. To clarify the presentation, however, we have refocused the presentation, restricting it to data for monitors sited in or within 15 kilometers of a Class I area,<sup>190</sup> and note that the results are little changed, continuing to call into question the adequacy of the current standard. As shown in Table 3, the dataset in the refocused presentation, which now spans 1998 up through 2013, includes 17 Class I areas for which monitors were identified in this manner. For context, we note that this represents nearly a quarter of the Class I areas for which there are O<sub>3</sub> monitors within 15 km.<sup>191</sup>

In recognition of the influence that other environmental factors can exert in the natural environment on the relationship between ambient O<sub>3</sub> exposures and RBL, potentially modifying the impact predicted by the E–R functions, the PA and proposal took particular note of the occurrence of 3-year average W126 index values at or above 19 ppm-hrs. In the re-focused analysis in Table 3, there are 11 areas, distributed across four states in two NOAA climatic regions, for which the 3-year W126 exposure index values ranged at or above 19 ppm-hrs, a value for which the corresponding median species RBL estimate for a growing season’s exposure is 6%, a magnitude termed “unacceptably high” by CASAC (Frey, 2014c, p. 13). The highest 3-year W126 index values in these 11 areas ranged from 19.0 up to 22.2 ppm-hrs, a cumulative seasonal exposure for which the median species RBL estimate is 9% for a single growing season. The annual W126 index values range above 19 ppm-hrs in 15 of the areas in the re-focused table provided here; these areas are distributed across six states (AZ, CA, CO, KY, SD, UT) and four regions (West, Southwest, West North Central and Central).<sup>192</sup> The highest index values in the areas with annual index values above 19 ppm-hrs range from 19.1 to 26.9 ppm-hrs. As is to be expected from the focus on a smaller dataset, the number of states with 1-year W126 index values above 19 ppm-hrs is smaller in the refocused analysis (15 as compared to 20), although the number of regions affected is the same. More importantly, however, the number of areas with 3-year W126 index values at or above 19 ppm-hrs is the same, 11 Class I areas across two regions, supporting the prior conclusions.

TABLE 3—O<sub>3</sub> CONCENTRATIONS FOR CLASS I AREAS DURING PERIOD FROM 1998 TO 2013 THAT MET THE CURRENT STANDARD AND WHERE 3-YEAR AVERAGE W126 INDEX VALUE WAS AT OR ABOVE 15 ppm-hrs

Class I area (distance away, if monitor is not at/within boundaries)	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
Bridger Wilderness Area <sup>QA, DF</sup> (8.9 km).	WY/Sublette .....	70–72	16.2–17.0	13.9–18.8	4
Canyonlands National Park <sup>QA, DF, PP</sup> .	UT/San Juan .....	70–73	15.4–19.5 (2, 19.1–19.5)	9.6–23.6 (4, 19.2–23.6)	8
Chiricahua National Monument <sup>DF, PP</sup> (12 km).	AZ/Cochise .....	69–73	15.2–19.8 (1, 19.8)	11.7–21.9 (2, 19.8–21.9)	10
Grand Canyon National Park <sup>QA, DF, PP</sup> .	AZ/Coconino .....	68–74	15.3–22.2 (7, 19.1–22.2)	10.1–26.9 (6, 19.8–26.9)	12
Desolation Wilderness <sup>PP</sup> (3.9 km) ..	CA/EI Dorado .....	75	19.8 (1, 19.8)	15.6–22.9 (2, 21.0–22.9)	1

<sup>190</sup> The 15 km distance was selected as a natural breakpoint in distance of O<sub>3</sub> monitoring sites from Class I areas and as still providing similar surroundings to those occurring in the Class I area. We note that given the strict restrictions on

structures and access within some of these areas, it is common for monitors intended to collect data pertaining to air quality in these types of areas to be sited outside their boundaries.

<sup>191</sup> There is an O<sub>3</sub> monitor within fewer than 15% of all Class I areas, and fewer than half of all Class I areas have a monitor within 15 km.

<sup>192</sup> This compares to 20 areas in eight states and four regions in the earlier analysis.

TABLE 3—O<sub>3</sub> CONCENTRATIONS FOR CLASS I AREAS DURING PERIOD FROM 1998 TO 2013 THAT MET THE CURRENT STANDARD AND WHERE 3-YEAR AVERAGE W126 INDEX VALUE WAS AT OR ABOVE 15 ppm-hrs—Continued

Class I area (distance away, if monitor is not at/ within boundaries)	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
Lassen Volcanic National Park DF, PP	CA/Shasta .....	72–74	15.3–15.6	11.5–19.1 (1, 19.1)	2
Mammoth Cave National Park BC, C, LP, RM, SM, VP, YP (0.1 km).	KY/Edmonson .....	74	15.7	12.3–22.0 (1, 22.0)	1
Maroon Bells-Snowmass Wilderness Area QA, DF (0.8 km).	CO/Gunnison .....	68–73	15.6–20.2 (1, 20.2)	13.0–23.8 (3, 21.3–23.8)	8
Mazatzal Wilderness DF, PP (10.9 km).	AZ/Maricopa .....	74–75	17.8–19.9 (1, 19.9)	10.3–26.2 (3, 19.7–26.2)	2
Mesa Verde National Park DF .....	CO/Montezuma .....	67–73	15.4–20.7 (1, 20.7)	10.7–23.4 (4, 19.5–23.4)	11
Petrified Forest National Park C .....	AZ/Navajo .....	70	15.4–16.9	12.7–18.6	2
Rocky Mountain National Park QA, DF, PP (0.9 km).	CO/Larimer .....	73–74	15.3–18.4	8.3–26.2 (4, 19.4–26.2)	5
Saguaro National Park DF, PP (0.1 km)**.	AZ/Pima .....	69–74	15.4–19.0 (1, 19.0)	7.3–22.9 (3, 19.6–22.9)	6
Superstition Wilderness Area (6.3, 14.9 km and 7.2 km)**.	AZ/Gila .....	72–75	16.6–20.9 (2, 19.0–20.9)	13.8–25.5 (4, 19.0–25.5)	5
	AZ/Maricopa .....	70–75	15–20.2 (1, 20.2)	6.3–23.9 (4, 19.6–23.9)	4
	AZ/Pinal .....	72–75	15.3–21.1 (1, 21.1)	10.2–24.7 (4, 21.4–24.7)	7
Weminuche Wilderness Area QA, DF, PP (14.9 km).	CO/La Plata .....	70–74	15.1–19.1 (1, 19.1)	10.8–21.0 (2, 20.8–21.0)	6
Wind Cave National Park QA, PP .....	SD/Custer .....	70	15.4	12.3–20.5 (1, 20.5)	1
Zion National Park QA, DF, PP (3.6 km).	UT/Washington .....	70–73	17.0–20.1 (2, 19.4–20.1)	14.2–23.2 (3, 19.8–23.2)	6

\*Based on hourly O<sub>3</sub> concentration data retrieved from AQS on June 25, 2014, and additional CASTNET data downloaded from [http://java.epa.gov/castnet/epa\\_jsp/prepackageddata.jsp](http://java.epa.gov/castnet/epa_jsp/prepackageddata.jsp) on June 25, 2014. Design values shown above are derived in accordance with Appendix P to 40 CFR Part 50. Annual W126 index values are derived as described in section IV.A.1 above; three consecutive year annual values are averaged for 3-year averages. Prior to presentation, both types of W126 index values are rounded to one decimal place. The full list of monitoring site identifiers and individual statistics is available in the docket for this rulemaking.

\*\*No monitor was sited within these Areas and multiple monitors were sited within 15 km. Data for the closest monitor per county are presented.

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>), NPS (<http://www.nps.gov/pefo/planyourvisit/upload/Common-Plants-Site-Bulletin-sb-2013.pdf>) and Phillips and Comus (2000).

As support for their view that the Class I area analysis is too uncertain to provide a basis for the Administrator's proposed conclusion that the current standard is not adequate, some commenters stated that forests in Class I areas were composed of mature trees and that the tree seedling E–R functions do not predict growth impacts in mature forests. The EPA disagrees with the commenters' statement that Class I areas are only made up of mature trees. Seedlings exist throughout forests as part of the natural process of replacing aging trees and overstory trees affected by periodic disturbances.<sup>193</sup> Seedlings also tend to occur in areas affected by natural disturbances, such as fires, insect infestations and flooding, and such disturbances are common in many natural forests. As noted above, information newly available in this review strengthens our understanding regarding O<sub>3</sub> effects on mature trees for

<sup>193</sup> Basic information on forest processes, including the role of seedlings is available at: [http://www.na.fs.fed.us/stewardship/pubs/NE\\_forest\\_regeneration\\_handbook\\_revision\\_130829\\_desktop.pdf](http://www.na.fs.fed.us/stewardship/pubs/NE_forest_regeneration_handbook_revision_130829_desktop.pdf).

aspen, an important and O<sub>3</sub>-sensitive species (U.S. EPA, 2013, section 9.6.3.2).

One commenter additionally stated that the EPA has not shown reduced biomass to be adverse to public welfare, variously citing individual studies, most of which are not considering O<sub>3</sub>, as support for their view that such an effect of O<sub>3</sub> may not occur in the environment and may be of no significance if it does. With regard to the occurrence of O<sub>3</sub>-related reduced growth in the field, we note the strength of the evidence from field OTC studies on which the E–R functions are based, and evidence from comparative studies with open-air chamberless control treatments suggests that characteristics particular to the OTC did not significantly affect plant response (U.S. EPA, 2013, p. 9–5). Thus, we view the OTC systems as combining aspects of controlled exposure systems with field conditions to facilitate a study providing data that represent the role of the studied pollutant in a natural system.

Further, we disagree with the commenters on the significance of O<sub>3</sub>-

attributable reduced growth in natural ecosystems. Even in the circumstances cited by the commenter (*e.g.*, subsequent to large-scale disturbances, nutrient limited system, multigeneration exposure), O<sub>3</sub> can affect growth of seedlings and older trees, with the potential for effects on ecosystem productivity, handicapping the sensitive species and affecting community dynamics and associated community composition, as well as ecosystem hydrologic cycles (U.S. EPA, 2013, p. 1–8). For example, two recent studies report on the role of O<sub>3</sub> exposure in affecting water use in a mixed deciduous forest and indicated that O<sub>3</sub> increased water use in the forest and also reduced growth rate (U.S. EPA, 2013, p. 9–43, McLaughlin, 2007a, 2007b). Contrary to the lesser effects implied by the commenters, the authors of these two studies noted implications of their findings with regard to the potential for effects to be amplified under conditions of increased temperature and associated reduced water availability (McLaughlin, 2007a). We additionally note comments from

the CASAC, summarized above, in which it concurs with a focus on biomass loss and the use of RBL estimates, calling biomass loss in trees a “relevant surrogate for damage to tree growth” that affects an array of ecosystem services (Frey, 2014c, p. 10), and identifies 6% RBL as “unacceptably high” (Frey, 2014c, p. 13). The evidence we presented includes evidence related to RBL estimates above that benchmark. Thus, while we agree that some reductions in tree growth may not be concluded to be adverse to public welfare, we disagree with commenters that we have not presented the evidence, which includes RBL estimates well above the 6% magnitude identified by CASAC, that supports the Administrator’s judgments on adversity that may be indicated by such estimates and her conclusion that adequate protection is not provided by the current standard, as described in section IV.B.3 below.

Some commenters disagree with the EPA’s consideration of the Class I areas analysis, stating that it is not appropriate for the EPA to evaluate the level of protection offered by the current primary O<sub>3</sub> standard under current conditions due to the long-range transport of O<sub>3</sub> and O<sub>3</sub> precursors to Class I areas from upwind non-attainment areas. It is the view of these commenters that once the upwind areas make emissions reductions to attain the current standard, downwind areas will see improvements in air quality and decreasing W126 levels. In support of this view, commenters point to several modeling analyses. Some commenters point to air quality modeling conducted by an environmental consultant that projects all sites to have W126 index values below 13 ppm-hrs when emissions are adjusted such that all upwind monitors are modeled to meet the current standard. Detailed methodology, results and references for the commenter’s modeling analysis were not provided, precluding a thorough evaluation and comparison to the EPA’s modeling. While the EPA agrees that transport of O<sub>3</sub> and O<sub>3</sub> precursors can affect downwind monitors, we disagree with commenters regarding the conclusions that are appropriate to draw from modeling simulations for the reasons noted below.

As support for their view that the current standard provides adequate protection, some commenters pointed to estimates drawn from the EPA’s air quality modeling performed for the RIA, stating that this modeling for an alternative standard level of 70 ppb indicates “only a handful” of monitoring sites approaching as high as

13 ppm-hrs as a 3-year average (*e.g.*, UARG, p. 76). These commenters further point to the WREA modeling, noting that those estimates project that attainment of the current standard would result in only 5 sites above 15 ppm-hrs. Based on these statements, these commenters state that the current standard is likely to provide conditions with no site having a monitor over 17 ppm-hrs and a “minimal number” likely exceeding 13 ppm-hrs (*e.g.*, UARG, p. 77). We disagree with commenters’ interpretation of the modeling information from the two different assessments. As we summarized in section IV.C.1 of the proposal with regard to the WREA modeling, the modeling estimates are each based on a single set of precursor emissions reductions that are estimated to achieve the desired target conditions, which is also the case for the RIA modeling<sup>194</sup> (U.S. EPA, 2014c, pp. 5–40 to 5–41; see also section 1.2.2 of the 2014 RIA).

As noted in section IV.A.2 above, and in the proposal, the model-adjusted air quality in the WREA scenario for the current standard does not represent an optimized control scenario that just meets the current standard, but rather characterizes one potential distribution of air quality across a region when all monitor locations meet the standard (79 FR 75322; U.S. EPA, 2014b, section 4.3.4.2). Alternate precursor emissions reductions would be expected to produce different patterns of O<sub>3</sub> concentrations and associated differences in W126 index values. Specifically, the precursor emissions reductions scenarios examined in the WREA focuses on regional reductions over broad areas rather than localized cuts that may focus more narrowly on areas violating the current standard (U.S. EPA, 2014b, p. 4–35). The assumption of regionally determined across-the-board emissions reductions is a source of potential uncertainty with the potential to overestimate W126 scenario benefits (U.S. EPA, 2014b, Table 4–5 [row G]). The application of emissions reductions to all locations in each region to bring down the highest monitor in the region to meet the

<sup>194</sup> Although commenters cite to both analyses as if providing the same information, there are many differences in specific aspects of the RIA approach from that of the WREA, which derive, at least in part, from their very different purposes. The RIA is not developed for consideration in the NAAQS review. Rather, it is intended to provide insights and analysis of an illustrative control strategy that states might adopt to meet the revised standard. The EPA does not consider this analysis informative to consideration of the protection provided by the current standard, and the results of the RIA have not been considered in the EPA’s decisions on the O<sub>3</sub> standards.

current standard could potentially lead to W126 index underestimates at some locations, as noted in the WREA: “[w]hile the scenarios implemented in this analysis show that [] bringing down the highest monitor in a region would lead to reductions below the targeted level through the rest of the region, to the extent that the regional reductions from on-the-books controls are supplemented with more local controls the additional benefit may be overestimated” (U.S. EPA, 2014b, p. 4–36; U.S. EPA, 2014c, pp. 5–40 to 5–41). This point was emphasized by CASAC in their comments on the 2nd draft WREA. CASAC noted that, “[m]eeting a target level at the highest monitor requires substantial reductions below the targeted level through the rest of the region” and stated that “[t]his artificial simulation does not represent an actual control strategy and may conflate differences in control strategies required to meet different standards” (Frey, 2014b, p. 2).

Due to the uncertainty about what actual future emissions control strategies might be and their associated emissions reductions, and the impact such uncertainty might have on modeling estimates involving reductions from recent conditions, we believe it is important to place weight on ambient air monitoring data for recent conditions in drawing conclusions regarding W126 index values that would be expected in areas that meet the current standard. The analysis of air quality data for Class I areas described in the proposal, and updated in Table 3 above (1998–2013), indicates the occurrence of 3-year W126 exposure index values well above 19 ppm-hrs, a cumulative exposure value for which CASAC termed the associated median RBL estimate “unacceptably high,” in multiple Class I areas that meet the current standard (79 FR 75312, December 17, 2014, Table 7; updated in Table 3 above). Additionally, analysis of recent air quality data (2011–2013) for all locations across the U.S. indicates 10 monitor locations distributed across two NOAA climatic regions that meet the current standard and at which 3-year W126 index values are above 19 ppm-hrs, with the highest values extending up to 23 ppm-hrs (Wells, 2015b).

In support of their view that the EPA’s modeling supports the conclusion that W126 index values of interest are achieved under the current secondary standard, some commenters additionally state that the W126 values in the WREA are overestimated in unmonitored rural areas due to the much greater prevalence of urban monitors across the U.S. The EPA

disagrees with this conclusion. In order to estimate O<sub>3</sub> concentrations in grid cells across a national-scale spatial surface, the WREA applied the VNA spatial interpolation technique after applying the HDDM technique to adjust O<sub>3</sub> concentrations at monitoring sites based on the emissions reductions necessary to just meet the current standard. In estimating concentrations in unmonitored areas, the VNA method considers only the “neighboring” monitors, using an inverse distance squared weighting formula, which assigns the greatest influence to the nearest neighboring monitor (U.S. EPA, 2014b, p. 4A–6). By this approach, monitors in less-densely monitored areas contribute to the concentration estimates over much larger areas than do monitors in more-densely monitored areas. In an urban area, neighboring monitors may be quite close to one another, such that any one monitor may only be influencing concentration estimates for a handful of spatial grid cells in the immediate vicinity. By contrast, monitors in rural areas may influence hundreds of grid cells. A specific example of this is the monitor in Great Basin National Park in eastern Nevada. The VNA algorithm assigns very high weights to this monitor for all of the grid cells covering a 100 km radius around it, simply because there are no other monitors in that area and it is the closest. On the other hand, a monitor near downtown Las Vegas may only get a high weight for, and thus exert influence on the concentration estimate in, the one grid cell containing it. We agree with the commenter that urban monitors may influence the spatial surface for some distance away from the urban areas, although the influence wanes with increasing distance from that area and decreasing distance to the next closest monitor. As we lack data for the intervening locations, however, we have no reason to conclude that the VNA surface is overestimating the W126 index values. Further, as was summarized in section IV.A.2 above, and in the WREA, the PA and the proposal (U.S. EPA, 2014b, Table 6–27, section 8.5; U.S. EPA, 2014c, p. 5–49; 79 FR 75323, December 17, 2014), the VNA approach results in a lowering of the highest W126 index values at monitoring sites, which contributes to underestimates of the highest W126 index values in each region.

In support of their view that the current standard is adequate, some industry commenters additionally cite WREA analyses for the current standard scenario, including the W126 index

estimates in national parks, as showing that the current standard provides more than adequate protection, with alternative scenarios providing only marginal and increasingly uncertain benefits. As we noted in the proposal and section IV.A.2 above, there are an array of uncertainties associated with the W126 index estimates, in the current standard scenario and in the other scenarios, which, as they are inputs to the vegetation risk analyses, are propagated into those analyses (79 FR 75323; December 17, 2014). As a result, consistent with the approach in the proposal, the Administrator has not based her decision with regard to adequacy of the current standard in this review on these air quality scenario analyses.

In support of their view that the current standard provides adequate protection and should not be revised, some commenters described their concerns with any consideration of visible foliar injury in the decision regarding the secondary standard. These commenters variously stated that visible foliar injury cannot be reliably evaluated for adversity given lack of available information, is not an adverse effect on public welfare that must be addressed through a secondary standard, and is not directly relatable to growth suppression (and the EPA’s use of RBL captures that effect anyway). Additionally, some state that any associated ecosystem services effects are not quantifiable. In sum, the view of these commenters is that it is not appropriate for the Administrator to place any weight on this O<sub>3</sub> effect in determining the adequacy of the current standard. As an initial matter, the EPA agrees with the comment that the current evidence does not include an approach for relating visible foliar injury to growth suppression,<sup>195</sup> as recognized in section IV.A.1.b above. Further, we note that, similar to decisions in past O<sub>3</sub> reviews, the Administrator’s proposed decision in this review recognized the “complexities and limitations in the evidence base regarding characterizing air quality conditions with respect to

<sup>195</sup> The current evidence indicates that “[t]he significance of O<sub>3</sub> injury at the leaf and whole plant levels depends on how much of the total leaf area of the plant has been affected, as well as the plant’s age, size, developmental stage, and degree of functional redundancy among the existing leaf area” and “in some cases, visible foliar symptoms have been correlated with decreased vegetative growth . . . and with impaired reproductive function” (U.S. EPA, 2013, p. 9–39). The ISA concludes, however, “it is not presently possible to determine, with consistency across species and environments, what degree of injury at the leaf level has significance to the vigor of the whole plant” (U.S. EPA, 2013, p. 9–39).

the magnitude and extent of risk for visible foliar injury” and the “challenges of associated judgments with regard to adversity of such effects to public welfare” (79 FR 75336; December 17, 2014). Contrary to the implications of the commenters, although the Administrator took into consideration the potential for adverse effects on public welfare from visible foliar injury, she placed weight primarily on growth-related effects of O<sub>3</sub>, both in her proposed decision on adequacy and with regard to proposed judgments on what revisions would be appropriate. Although visible foliar injury may impact the public welfare and accordingly has the potential to be adverse to the public welfare (as noted in section IV.B.2 of the proposal), the Administrator placed less weight on visible foliar injury considerations in identifying what revisions to the standard would be appropriate to propose. In considering these effects for this purpose, she recognized “significant challenges” 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” (79 FR 75349; December 17, 2014). As summarized in section IV.A.1.a above, the evidence demonstrates a causal relationship of O<sub>3</sub> with visible foliar injury. Accordingly, we note that the uncertainty associated with visible foliar injury is not with regard to whether O<sub>3</sub> causes visible foliar injury. Rather, the uncertainty is, as discussed in sections IV.A.1.b and IV.A.3 above, with the lack of established, quantitative exposure-response functions that document visible foliar injury severity and incidence under varying air quality and environmental conditions and information to support associated judgments on the significance of such responses with regard to associated public welfare impacts. As with the Administrator’s proposed decisions on the standard, such considerations also informed her final decisions, described in sections IV.B.3 and IV.C.3 below.

In support of their view that the current standard should be retained, some commenters note the WREA finding for the current standard scenario of no U.S. counties with RYL estimates at or above 5%, the RYL value emphasized by CASAC and state that policy reasons provide support for not focusing on crops in the decision; other commenters state that additional studies on crops and air quality are needed. As

described previously in this section, and in section IV.A.2 above, an aspect of uncertainties associated with the WREA air quality scenarios, including the current standard scenario, is underestimation of the highest W126 index values, contributing to underestimates in the effects associated with the current standard scenario. The EPA agrees with commenters that additional studies on crops and air quality will be useful to future reviews. Additionally, however, as noted above, the Administrator's proposed conclusion on adequacy of the current standard, as well as her final decision described in section IV.B.3 below, gives less weight to consideration of effects on agricultural crops in recognition of the complicating role of heavy management in that area.

Lastly, we note that many commenters cited the costs of compliance as supporting their view that the standard should not be revised, although as we have described in section I.B above, the EPA may not consider the costs of compliance in determining what standard is requisite to protect public welfare from known or anticipated adverse effects.

### 3. Administrator's Conclusions on the Need for Revision

Having carefully considered the advice from CASAC and public comments, as discussed above, the Administrator believes that the fundamental scientific conclusions on the welfare effects of O<sub>3</sub> in ambient air reached in the ISA and summarized in the PA and in section IV.B of the proposal remain valid. Additionally, the Administrator believes the judgments she reached in the proposal (section IV.D.3) with regard to consideration of the evidence and quantitative assessments and advice from CASAC remain appropriate. Thus, as described below, the Administrator concludes that the current secondary standard is not requisite to protect public welfare from known and anticipated adverse effects associated with the presence of O<sub>3</sub> in the ambient air and that revision is needed to provide additional protection.

In considering the adequacy of the current secondary O<sub>3</sub> standard, the Administrator has carefully considered the available evidence, analyses and conclusions contained in the ISA, including information newly available in this review; the information, quantitative assessments, considerations and conclusions presented in the PA; the advice and recommendations from CASAC; and public comments. The Administrator gives primary consideration to the evidence of growth

effects in well-studied tree species and information, presented in the PA and represented with a narrower focus in section IV.B.2 above, on cumulative exposures occurring in Class I areas when the current standard is met. This information indicates the occurrence of exposures associated with Class I areas during periods when the current standard is met for which associated estimates of growth effects, in terms of the tree seedling RBL in the median species for which E-R functions have been established, extend above a magnitude considered to be "unacceptably high" by CASAC. This analysis estimated such cumulative exposures occurring under the current standard for nearly a dozen areas, distributed across two NOAA climatic regions of the U.S. The Administrator gives particular weight to this analysis, given its focus in Class I areas. Such an emphasis on lands afforded special government protections, such as national parks and forests, wildlife refuges, and wilderness areas, some of which are designated Class I areas under the CAA, is consistent with such emphasis in the 2008 revision of the secondary standard (73 FR 16485, March 27, 2008). As noted in section IV.A above, Congress has set such lands 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. The Administrator additionally recognizes 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 those lands, as well as for visitors to those areas.

As noted in prior reviews, judgments regarding effects that are adverse to public welfare consider the intended use of the ecological receptors, resources and ecosystems affected. Thus, the Administrator recognizes that the median RBL estimate for the studied species is a quantitative tool within a larger framework of considerations pertaining to the public welfare significance of O<sub>3</sub> effects on the public welfare. Such considerations include effects that are associated with effects on growth and that the ISA has determined to be causally or likely causally related to O<sub>3</sub> in ambient air, yet for which there are greater uncertainties affecting our estimates of impacts on public welfare. These other effects include reduced productivity in terrestrial ecosystems, reduced carbon

sequestration in terrestrial ecosystems, alteration of terrestrial community composition, alteration of below-grown biogeochemical cycles, and alteration of terrestrial ecosystem water cycles, as summarized in section IV.A.1. Thus, in her attention to CASAC's characterization of a 6% estimate for tree seedling RBL in the median studied species as "unacceptably high", the Administrator, while mindful of uncertainties with regard to the magnitude of growth impact that might be expected in mature trees, is also mindful of related, broader, ecosystem-level effects for which our tools for quantitative estimates are more uncertain and those for which the policy foundation for consideration of public welfare impacts is less well established. She finds her consideration of tree growth effects consistent with CASAC advice regarding consideration of O<sub>3</sub>-related biomass loss as a surrogate for the broader array of O<sub>3</sub> effects at the plant and ecosystem levels.

The Administrator also recognizes that O<sub>3</sub>-related effects on sensitive vegetation can occur in other areas that have not been afforded special federal protections, including 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. In her consideration of the evidence and quantitative information of O<sub>3</sub> effects on crops, the Administrator recognizes the complexity of considering adverse O<sub>3</sub> impacts to public welfare due to the heavy management common for achieving optimum yields and market factors that influence associated services. In so doing, she notes that her judgments that place emphasis on the protection of forested ecosystems inherently also recognize a level of protection for crops. Additionally, for vegetation used for residential or commercial ornamental purposes, the Administrator believes that there is not adequate information specific to vegetation used for those purposes, 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.

The Administrator also takes note of the long-established evidence of consistent association of the presence of visible foliar injury with O<sub>3</sub> exposure and the currently available information that indicates the occurrence of visible foliar injury in sensitive species of



vegetation during recent air quality in public forests across the U.S. She additionally notes the PA conclusions regarding difficulties in quantitatively relating visible foliar injury symptoms to vegetation effects such as growth or related ecosystem effects. As at the time of the last review, the Administrator believes that the degree to which such effects should be considered to be adverse depends on the intended use of the vegetation and its significance. The Administrator also believes that the significance of O<sub>3</sub>-induced visible foliar injury depends on the extent and severity of the injury and takes note of studies in the evidence base documenting increased severity and/or prevalence with higher O<sub>3</sub> exposures. However, the Administrator takes note of limitations in the available information with regard to judging the extent to which the extent and severity of visible foliar injury occurrence associated with conditions allowed by the current standard may be considered adverse to public welfare.

Based on these considerations, and taking into consideration the advice and recommendations of CASAC, the Administrator concludes that the protection afforded by the current secondary O<sub>3</sub> standard is not sufficient and that the standard needs to be revised to provide additional protection from known and anticipated adverse effects to public welfare, related to effects on sensitive vegetation and ecosystems, most particularly those occurring in Class I areas. The Administrator additionally recognizes 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 those lands, as well as for visitors to those areas. Given 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 areas contain O<sub>3</sub>-sensitive vegetation, the Administrator further concludes that it is appropriate to revise the secondary standard in part to provide increased protection against O<sub>3</sub>-caused impairment to vegetation and ecosystems in such areas, which have been specially protected to provide public welfare benefits. She further notes that a revised standard would provide increased protection for other growth-related effects, including for crop yield loss, reduced carbon storage and for areas for which it is more difficult to determine public welfare significance, as recognized in section IV.A.3 above, as well other welfare

effects of O<sub>3</sub>, such as visible foliar injury.

### *C. Conclusions on Revision of the Secondary Standard*

The elements of the standard—indicator, averaging time, form, and level—serve to define the standard and are considered collectively in evaluating the welfare protection afforded by the secondary standard. Section IV.C.1 below summarizes the basis for the proposed revision. Significant comments received from the public on the proposal are discussed in section IV.C.2 and the Administrator's final decision on revisions to the secondary standard is described in section IV.C.3.

#### 1. Basis for Proposed Revision

At the time of proposal, in considering what revisions to the secondary standard would be appropriate, the Administrator considered the ISA conclusions regarding the weight of the evidence for a range of welfare effects associated with O<sub>3</sub> 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; CASAC advice; and public comments received as of that date in the review. In the paragraphs below, we summarize the proposal presentation with regard to key aspects of the PA considerations, advice from the CASAC, air quality analyses of different air quality metrics and the Administrator's proposed conclusions, drawing from section IV.E of the proposal.

#### a. Considerations and Conclusions in the PA

As summarized in the proposal, in identifying alternative secondary standards appropriate to consider in this review, the PA focused on standards based on a cumulative, seasonal, concentration-weighted form consistent with the CASAC advice in the current and last review. Based on conclusions of the ISA, as also summarized in section IV.A above, the PA considered a cumulative, seasonal, concentration-weighted exposure index to provide the most scientifically defensible approach for characterizing vegetation response to ambient O<sub>3</sub> and comparing study findings, as well as for defining indices

for vegetation protection, as summarized in the proposal section IV.E.2.a. With regard to the appropriate index, the PA considered the evidence for a number of different such indices, as described in the proposal, and noted the ISA conclusion that the W126 index has some important advantages over other similarly weighted indices. The PA additionally considered the appropriate diurnal and seasonal exposure periods in a given year by which to define the seasonal W126 index and based on the evidence in the ISA and CASAC advice, as summarized in the proposal, decided on the 12-hour daylight window (8:00 a.m. to 8:00 p.m.) and the 3-consecutive-month period providing the maximum W126 index value.

Based on these considerations, the PA concluded it to be appropriate to retain the current indicator of O<sub>3</sub> and to consider a secondary standard form that is an average of the seasonal W126 index values (derived as described in section IV.A.1.c above) across three consecutive years (U.S. EPA, 2014c, section 6.6). In so doing, the PA 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 3-year form (U.S. EPA, 2014c, pp. 6–30). The PA concluded a 3-year form to be appropriate for a standard intended to provide 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 might result from a single-year form. (U.S. EPA, 2014c, section 6.6).

As summarized in the proposal, the PA noted 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, it is essential to consider the species present and their public welfare significance, together with the magnitude of the ambient concentrations in drawing conclusions regarding the significance or magnitude of public welfare impacts. 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. In considering an appropriate range of levels to consider for an alternative standard, the PA primarily considered tree growth, crop yield loss, and visible foliar injury, as well as impacts on the associated ecosystem services, while noting key uncertainties and limitations.

In specifically evaluating exposure levels, in terms of the W126 index, as to their appropriateness for consideration in this review with regard to providing the desired level of vegetation protection for a revised secondary standard, the PA focused particularly on RBL estimates for the median across the 11 tree species for which robust E-R functions are available. Table 4 below presents these estimates (U.S. EPA, 2014c, Appendix 5C, Table 5C-3; also summarized in Table 8 of the proposal). In so doing and recognizing the longstanding, strong evidence base supporting these relationships, the PA also noted

uncertainties regarding inter-study variability for some species, as well as with regard to the extent to which tree seedling E-R functions can be used to represent mature trees. As summarized in the proposal, the PA conclusions on a range of W126 levels appropriate to consider are based on specific advice from CASAC with regard to median tree seedling RBL estimates that might be considered unacceptably high (6%), as well as its judgment on a RBL benchmark (2%) for identification of the lower end of a W126 index value range for consideration that might give more emphasis to the more sensitive tree seedlings (Frey, 2014c, p. 14).<sup>196</sup>

TABLE 4—TREE SEEDLING BIOMASS LOSS AND CROP YIELD LOSS ESTIMATED FOR O<sub>3</sub> EXPOSURE OVER A SEASON

W126 index value for exposure period	Tree seedling biomass loss <sup>A</sup>		Crop yield loss <sup>B</sup>	
	Median value	Individual species	Median value	Individual species
23 ppm-hrs .....	Median species w. 7.6% loss	≤ 2% loss: 3/11 species .... ≤ 5% loss: 4/11 species .... ≤ 10% loss: 8/11 species ... ≤ 15% loss: 10/11 species ... >40% loss: 1/11 species ...	Median species w. 8.8% loss	≤ 5% loss: 4/10 species >5, <10% loss: 1/10 species >10, <20% loss: 4/10 species >20: 1/10 species
22 ppm-hrs .....	Median species w. 7.2% loss	≤ 2% loss: 3/11 species .... ≤ 5% loss: 4/11 species .... ≤ 10% loss: 7/11 species ... ≤ 15% loss: 10/11 species ... >40% loss: 1/11 species ...	Median species w. 8.2% loss	≤ 5% loss: 4/10 species >5, <10% loss: 1/10 species >10, <20% loss: 4/10 species >20: 1/10 species
21 ppm-hrs .....	Median species w. 6.8% loss	≤ 2% loss: 3/11 species .... ≤ 5% loss: 4/11 species .... ≤ 10% loss: 7/11 species ... ≤ 15% loss: 10/11 species ... >40% loss: 1/11 species ...	Median species w. 7.7% loss	≤ 5% loss: 4/10 species >5, <10% loss: 3/10 species >10, <20% loss: 3/10 species
20 ppm-hrs .....	Median species w. 6.4% loss	≤ 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. 7.1% loss	≤ 5% loss: 5/10 species >5, <10% loss: 3/10 species >10, <20% loss: 2/10 species
19 ppm-hrs .....	Median species w. 6.0% loss	≤ 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	≤ 5% loss: 5/10 species >5, <10% loss: 3/10 species >10, <20% loss: 2/10 species
18 ppm-hrs .....	Median species w. 5.7% loss	≤ 2% loss: 5/11 species .... ≤ 5% loss: 5/11 species .... ≤ 10% loss: 7/11 species ... ≤ 15% loss: 10/11 species ... >30% loss: 1/11 species ...	Median species w. 5.7% loss	≤ 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	≤ 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	≤ 5% loss: 5/10 species >5, <10% loss: 3/10 species >10, <20% loss: 2/10 species
16 ppm-hrs .....	Median species w. 4.9% loss	≤ 2% loss: 5/11 species .... ≤ 5% loss: 6/11 species .... ≤ 10% loss: 10/11 species ... >30% loss: 1/11 species ...	Median species w. ≤5.0% loss	≤ 5% loss: 5/10 species >5, <10% loss: 4/10 species >10, <20% loss: 1/10 species
15 ppm-hrs .....	Median species w. 4.5% loss	≤ 2% loss: 5/11 species .... ≤ 5% loss: 6/11 species .... ≤ 10% loss: 10/11 species ... >30% loss: 1/11 species ...	Median species w. ≤5.0% loss	≤ 5% loss: 6/10 species >5, <10% loss: 4/10 species
14 ppm-hrs .....	Median species w. 4.2% loss	≤ 2% loss: 5/11 species .... ≤ 5% loss: 6/11 species .... ≤ 10% loss: 10/11 species ... >30% loss: 1/11 species ...	Median species w. ≤5.0% loss	≤ 5% loss: 6/10 species >5, <10% loss: 4/10 species
13 ppm-hrs .....	Median species w. 3.8% loss	≤ 2% loss: 5/11 species .... <5% loss: 7/11 species .... <10% loss: 10/11 species ... >20% loss: 1/11 species ...	Median species w. ≤5.0% loss	≤ 5% loss: 6/10 species >5, <10% loss: 4/10 species

<sup>196</sup> 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 of the proposal.

TABLE 4—TREE SEEDLING BIOMASS LOSS AND CROP YIELD LOSS ESTIMATED FOR O<sub>3</sub> EXPOSURE OVER A SEASON—Continued

W126 index value for exposure period	Tree seedling biomass loss <sup>A</sup>		Crop yield loss <sup>B</sup>	
	Median value	Individual species	Median value	Individual species
12 ppm-hrs .....	Median species w. 3.5% loss	≤ 2% loss: 5/11 species .... ≤ 5% loss: 8/11 species .... ≤10% loss: 10/11 species .... >20% loss: 1/11 species ...	Median species w. ≤5.0% loss	≤ 5% loss: 8/10 species >5, <10% loss: 2/10 species
11 ppm-hrs .....	Median species w. 3.1% loss	≤ 2% loss: 5/11 species .... ≤5% loss: 8/11 species ..... ≤10% loss: 10/11 species .... >20% loss: 1/11 species ...	Median species w. ≤5.0% loss	≤ 5% loss: 9/10 species >5, <10% loss: 1/10 species
10 ppm-hrs .....	Median species w. 2.8% loss	≤ 2% loss: 5/11 species .... ≤ 5% loss: 9/11 species .... <10% loss: 10/11 species .... >20% loss: 1/11 species ...	Median species w. ≤5.0% loss	≤ 5% loss: 9/10 species >5, <10% loss: 1/10 species
9 ppm-hrs .....	Median species w. 2.4% loss	≤ 2% loss: 5/11 species .... ≤ 5% loss: 10/11 species .. >20% loss: 1/11 species ...	Median species w. ≤5.0% loss	≤ 5% loss: all species
8 ppm-hrs .....	Median species w. 2.0% loss	≤ 2% loss: 5/11 species .... ≤ 5% loss: 10/11 species .. >15% loss: 1/11 species ...	Median species w. ≤5.0% loss	≤ 5% loss: all species
7 ppm-hrs .....	Median species w. <2.0% loss	≤ 2% loss: 7/11 species .... ≤5% loss: 10/11 species ... >15% loss: 1/11 species ...	Median species w. ≤5.0% loss	≤ 5% loss: all species

<sup>A</sup> Estimates here are based on the E–R functions for 11 species described in the WREA, section 6.2 and discussed in the PA, section 5.2.1. The cottonwood was excluded to address CASAC comments (Frey, 2014c; U.S. EPA, 2014b, U.S. EPA, 2014c, Appendix 6F). The median is the median of the 11 composite E–R functions (U.S. EPA, 2014c, Appendix 5C).

<sup>B</sup> Estimates here are based on the 10 E–R functions for crops described in the WREA, section 6.2 and discussed in the PA, section 5.3.1. The median is the median of the 10 composite E–R functions (U.S. EPA, 2014b; U.S. EPA, 2014c, Appendix 5C).

With regard to secondary standard revisions appropriate to consider in this review, as summarized in the proposal, the PA concluded it to be appropriate to consider a W126-based secondary standard with index values within the range of 7 to 17 ppm-hrs and a form averaged over 3 years (U.S. EPA, 2014c, section 6.7). The PA additionally recognized 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<sub>3</sub> standard.

The PA additionally recognized that to the extent the Administrator finds it useful to consider the public welfare protection that might be afforded by revising the level of the current standard, this is appropriately judged by evaluating the impact of associated O<sub>3</sub> exposures in terms of the cumulative seasonal W126-based index, an exposure metric considered appropriate for evaluating impacts on vegetation (U.S. EPA, 2014c, section 6.7). Accordingly, the PA included several air quality data analyses that might inform such consideration (U.S. EPA, 2014c, section 6.4). Additional air quality analyses were performed subsequent to the PA, described in the proposal and are summarized below.

b. CASAC Advice

Advice received from the CASAC during the current review, similar to that in the last review, recommended retaining O<sub>3</sub> as the indicator, while also recommending consideration of a secondary standard with a revised form and averaging time based on the W126 index (Frey, 2014c, p. iii). The CASAC concurred with the 12-hour period (8 a.m. to 8 p.m.) and 3-month summation period resulting in the maximum W126 index value, as described in the PA, while recommending a somewhat narrower range of levels from 7 ppm-hrs to 15 ppm-hrs. While the CASAC recommended a W126 index limited to a single year, in contrast with the PA’s conclusion that it was appropriate to consider the W126 index averaged across three years, it also noted that the Administrator may prefer, as a policy matter, to base the secondary standard on a 3-year averaging period. In such a case, the CASAC recommended revising downward the level for such a metric to avoid a seasonal W126 index value above a level in their recommended range in any given year of the 3-year period, indicating an upper end of 13 ppm-hrs as an example for such a 3-year average W126 index range (Frey, 2014c, p. iii and iv).

c. Air Quality Analyses

The proposal additionally summarized several analyses of air quality that considered relationships

between metrics based on a 3-year W126 index and based on the form and averaging time of the current standard, the “fourth-high” metric (U.S. EPA, 2014c, Chapter 2, Appendix 2B and section 6.4; Wells, 2014a), as well as describing the uncertainties and limitations associated with these analyses. The proposal concluded that these analyses suggest that, depending on the level, a standard of the current averaging time and form can be expected to control cumulative seasonal O<sub>3</sub> exposures to such that they may meet specific 3-year average W126 index values. The fourth-high and W126 metrics, and changes in the two metrics over the past decade, were found to be highly correlated (U.S. EPA, 2014c, section 6.4 and Appendix 2B; Wells, 2014a). From these analyses, it was concluded that future control programs designed to help meet a standard based on the fourth-high metric are also expected to result in reductions in values of the W126 metric (Wells, 2014a). Further, the second analysis also found that the Southwest and West NOAA climatic regions, which showed the greatest potential for sites to measure elevated cumulative, seasonal O<sub>3</sub> exposures without the occurrence of elevated daily maximum 8-hour average O<sub>3</sub> concentrations, exhibited the greatest reduction in W126 metric value per unit reduction in fourth-high metric (Wells, 2014a, Figures 5b and 12 and Table 6).

Analyses of the most recent periods studied in the two analyses (2009–2011 and 2011–2013) had similar findings regarding the highest W126 metric values occurring at monitoring sites that meet alternative levels of the fourth-high metric (U.S. EPA, 2014c, section 6.4; Wells, 2014a). In both analyses, the highest W126 metric values were in the Southwest and West NOAA climatic regions. In both analyses, no monitoring sites for which the fourth-high metric was at or below 70 ppb had a W126 metric value above 17 ppm-hrs (U.S. EPA, 2014c, Figure 2B–3b; Wells, 2014a, Table 4). All U.S. regions were represented in these subsets. In the 2011–2013 subset of sites for which the fourth-high metric was at or below a potential alternative primary standard level of 65 ppb, no monitoring sites had W126 metric values above 11 ppm-hrs (Wells, 2014a, Table 4).

#### d. Administrator's Proposed Conclusions

At the time of proposal, the Administrator concluded it to be appropriate to continue to use O<sub>3</sub> as the indicator for a secondary standard that is intended to address effects associated with exposure to O<sub>3</sub> alone and in combination with related photochemical oxidants. While the complex atmospheric chemistry in which O<sub>3</sub> plays a key role has been highlighted in this review, no alternatives to O<sub>3</sub> have been advanced as being a more appropriate surrogate for ambient photochemical oxidants and their effects on vegetation. The CASAC agreed that O<sub>3</sub> should be retained as the indicator for the standard (Frey, 2014c, p. iii). In proposing to retain O<sub>3</sub> as the indicator, the Administrator recognized that measures leading to reductions in ecosystem exposures to O<sub>3</sub> would also be expected to reduce exposures to other photochemical oxidants.

The Administrator proposed to retain the current averaging time and form and to revise the level of the current secondary standard to a level within the range of 0.065 to 0.070 ppm. She based this proposal on her provisional conclusions regarding the level of cumulative seasonal O<sub>3</sub> exposures that would provide the requisite protection against known or anticipated adverse effects to the public welfare and on a policy option that would provide this level of protection. With regard to the former, the Administrator concluded that in judging the extent of public welfare protection that might be afforded by a revised standard and whether it meets the appropriate level of protection, it is appropriate to use a cumulative, seasonal concentration-

weighted exposure metric. For this purpose, the Administrator concluded it to be appropriate to use the W126 index value, averaged across three years, with each year's value identified as that for the 3-month period yielding the highest seasonal value and with daily O<sub>3</sub> exposures within a 3-month period cumulated for the 12-hour period from 8:00 a.m. to 8:00 p.m.

To identify the range of cumulative seasonal exposures, in terms of the W126 index, expected to be associated with the appropriate degree of public welfare protection, the Administrator gave primary consideration to growth-related impacts, using tree seedling RBL estimates for a range of W126 exposure index values and CASAC advice regarding such estimates. Additionally taking into account judgments on important uncertainties and limitations inherent in the current available scientific evidence and quantitative assessments, and judgments regarding the extent to which different RBL estimates might be considered indicative of effects adverse to public welfare, the Administrator proposed that ambient O<sub>3</sub> concentrations resulting in cumulative seasonal O<sub>3</sub> 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. In identifying policy options for a revised secondary standard that would control exposures to such an extent, the Administrator considered the results of air quality analyses that examined the responsiveness of cumulative exposures (in terms of the W126 index) to O<sub>3</sub> reductions in response to the current and prior standard for which the form and averaging time are summarized as a fourth-high metric, and also examined the extent to which cumulative exposures (in terms of the W126 index) may be limited by alternative levels of a metric based on the current standard averaging time and form. Based on the results of these analyses, she proposed that revision of the level of the current secondary standard to within the range of 0.065 to 0.070 ppm would be expected to provide the requisite public welfare protection, depending on final judgments concerning such requisite protection.

#### 2. Comments on Proposed Revision

Significant comments from the public regarding revisions to the secondary standard are addressed in the subsections below. We first discuss comments related to our consideration of growth-related effects and visible

foliar injury in identifying appropriate revisions to the standard (sections IV.C.2.a and IV.C.2.b). Next, we address comments related to the use of the W126 metric in evaluating vegetation effects and public welfare protection and comments related to the form and averaging time for the revised standard (sections IV.C.2.c and IV.C.2.d). Comments on revisions to the level of the standard are described in section IV.C.2.e, and those related to the way in which today's rulemaking addresses the 2013 court remand are addressed in section IV.C.2.f. Other significant comments related to consideration of a revised secondary standard, and that are based on relevant factors, are addressed in the Response to Comments document.

#### a. Consideration of Growth-Related Effects

In considering public comments received on the consideration of growth-related effects of O<sub>3</sub> in the context of the proposed decision on a revised secondary standard, we first note related advice and comments from the CASAC provided during development of the PA, stating, as summarized in section IV.B.1.b above, 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). Additionally, in the context of different standard levels they considered appropriate for the EPA to consider, CASAC stated 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" (Frey, 2014c, p. 14).<sup>197</sup> 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).

In addition, regarding consideration of RBL 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

<sup>197</sup> The CASAC made this comment while focusing on Table 6–1 in the second draft PA and the entry for 17 ppm-hrs (Frey, 2014c, p. 14). That table was revised for inclusion in the final PA in consideration of CASAC comments on the E–R function for eastern cottonwood, and after that revision, the median RBL estimate for 17 ppm-hrs in the final table (see Table 4 above) is below the value of 6% that CASAC described in this way.

years” (Frey, 2014c, p. 14).<sup>198</sup> With regard to this benchmark, 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” in the PA (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 as a lower bound for the recommended range (Frey, 2014c, p. 14).<sup>199</sup>

With regard to consideration of effects on crops, in addition to their comments regarding a median species RYL over 5% yield loss, noted above (Frey, 2014c, p. 13), 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).

Comments from the public with regard to how the EPA considered growth-related effects in the proposed decision on a revised secondary standard varied. Generally, those commenters who recommended against revision of the standard expressed the view that RBL estimates based on the established E-R functions for the 11 studied species, and their pertinence to mature trees, were too uncertain to serve as a basis for judgments regarding public welfare protection afforded by the secondary standard. The EPA generally disagrees with this view, as discussed in section IV.B.2 above, and addressed in more detail in the Response to Comments document.

Some commenters also took note of the unclear basis for CASAC’s 2% benchmark, stating that the CASAC advice on this point is “not wholly scientific,” given that it referenced the 1996 workshop, which provided little specificity as to scientific basis for such a benchmark; based on this, the

commenters described this CASAC advice as a policy judgment and described the important role of the EPA’s judgment in such instances. As noted in section IV.E.3 of the proposal, we generally agree with these commenters regarding the unclear scientific basis for the 2% value. Consistent with this advice from CASAC, however, the range of levels for a revised secondary standard that the PA concluded was appropriate for the Administrator to consider did include a level for which the estimated median RBL across the 11 studied tree species would be 2%, as well as a level for which the median RBL would be below 2% (U.S. EPA, 2014c, section 6.7 and Tables 6–1 and 5C–3), and, as described in the proposal, the Administrator considered the conclusions of the PA in reaching her proposed decision that it was appropriate to consider a range for the revised secondary standard that did not focus on this benchmark. The Administrator has further considered and explained any differences from CASAC’s recommendations on this point in her final decision, as described in section IV.C.3 below.

Some of the state and local environmental agencies and organizations and environmental groups that supported the EPA’s proposed decision to revise the secondary standard additionally indicated their view that the EPA should give more weight to growth-related effects by setting the standard at a level for which the estimated RBL would be at or below 2% in the median studied species. In support of this recommendation, the commenters cited the CASAC advice and stated that the EPA’s rationale deviates from that advice with regard to consideration of RBL. In so doing, the commenters implied incorrectly that the EPA’s proposal did not put the most weight on the median RBL. In fact, in considering RBL as a metric for growth effects, the Administrator’s proposed conclusions focused solely on the median RBL estimates, indicating that appreciable weight was given to growth-related effects and on the median RBL. Additionally, the commenters implied that the EPA misconstrued the CASAC comment on 6% RBL to indicate that it was acceptable. Yet, the proposal notes CASAC’s view that a 6% RBL is “unacceptably high” nine times, and, in section IV.B.3 above, the Administrator takes note of this view in reaching the decision that the current standard should be revised. The EPA considers this statement from CASAC, provided in the context of considering effects related to different W126 index values, to be of

a different nature than CASAC advice discussed above that options for the EPA consideration “include” a level that aims for median RBL at or below 2%.

The comments that state that the standard should control cumulative exposures to levels for which the estimated median species RBL is at or below 2% provided little rationale beyond citing to CASAC advice. We note, however, that the CASAC did not specify that the revised secondary standard be set to limit cumulative exposures to that extent. Nor, in identifying a range of alternatives for the EPA to consider, did CASAC recommend that the EPA consider *only* W126 index levels associated with median RBL estimates at or below 2%. Rather, the CASAC stated that “it is appropriate to identify a range of levels of alternative W126-based standards that *includes* {emphasis added} levels that aim for not greater than 2% RBL for the median tree species” (Frey, 2014c, p. 14) and seven of the nine levels in the CASAC-recommended range of W126 index levels were associated with higher RBL estimates (as shown in Table 4 above).

In citing to CASAC advice, commenters quoted the CASAC characterization of a 2% RBL as “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, 2014, p. 14). Presumably to indicate reasoning for this statement, the subsequent sentence in the same CASAC letter referenced findings for biomass loss in aspen exposed to elevated O<sub>3</sub> over seven years, citing Wittig et al., 2009. As noted in the proposal, however, the way in which these findings would provide a basis for CASAC’s view with regard to 2% is unclear, as the original publication that is the source for the 7-year biomass loss value (King, et al., 2005) and which is cited in Wittig et al. (2009) indicates yearly RBL values during this 7-year exposure that are each well above 2%, and, in fact, are all above 20% (King, et al., 2005). In the same paragraph, the CASAC letter additionally referenced the report of the 1996 workshop sponsored by the Southern Oxidants Study group (Heck and Cowling, 1997, noted in section IV.A.3 above). The workshop report identified 1–2% per year growth reduction (based on a stated interest in avoiding 2% cumulative effects) as an appropriate endpoint for consideration of growth effects in trees, although an explicit rationale for the identified percentages is not provided

<sup>198</sup> 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 of the proposal.

<sup>199</sup> The CASAC made this comment while focusing on Table 6–1 in the second draft PA, which included odd-numbered W126 index values and in which the median RBL values were based on 12 species. 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 median RBL species estimate for both 7 ppm-hrs and 8 ppm-hrs are less than or equal to 2.0% in the final table (see Table 4 above and Table 5C–3 of the final PA).

(Frey, 2014c, p. 14).<sup>200</sup> Like the 1996 workshop, the CASAC describes 2% RBL as providing the basis for consideration of 7 ppm-hrs, the lower end of their recommended W126 range (Frey, 2014c, p. 14). As a result, the specific scientific basis for judging a value of 2% RBL in the median studied species as an appropriate benchmark of adverse impact for trees and other long-lived perennials is not clear, which, as described in the proposal, contributed to the Administrator noting the greater uncertainty regarding the extent to which estimates of benefits in terms of ecosystem services and reduced effects on vegetation at O<sub>3</sub> exposures below her identified range of 13 to 17 ppm-hrs might be judged significant to the public welfare.

Some commenters recommended revision of the standard to 7 ppm-hrs as a W126 form stating that such a change is needed to protect against climate change. In so doing, one commenter expressed the view that the relatively lesser weight the EPA placed on the WREA estimates of carbon storage (in terms of CO<sub>2</sub>) in consideration of a proposed revision to the secondary standard is inconsistent with the emphasis that the EPA placed on CO<sub>2</sub> emissions reductions estimated for the proposed Clean Power Plan (79 FR 34830, 34931–33). As support for this view of inconsistency, the commenter compared the WREA 30-year estimate of the amount of CO<sub>2</sub> removed from the air and stored in vegetation with estimated reductions in CO<sub>2</sub> emissions from power plants over a 4-year period. We note, however, some key distinctions between the two types of estimates which appropriately lead to different levels of emphasis by the EPA in the two actions. First, we note that the lengths of time pertaining to the two estimates that the commenter states to be “roughly equal” (e.g., ALA et al., p. 211) differ by more than a factor of seven (4 years compared to 30). Second, the CPP estimates are for reductions in CO<sub>2</sub> produced and emitted from power plants, while the WREA estimates are for amounts of CO<sub>2</sub> removed from the air and stored in vegetation as a result of plant photosynthesis occurring across the U.S. This leads to two important differences. The first is whether a ton of additional carbon uptake by plants is equal to a ton of reduced emissions from fossil fuels. This is still an active area of discussion due in part to the potentially transient

nature of the carbon storage in vegetation. The second is that there are much larger uncertainties involved in attempting to quantify the additional carbon uptake by plants which requires complex modeling of biological and ecological processes and their associated sources of uncertainty. Therefore, as summarized in section IV.C.3 below, the Administrator is judging, as at the time of proposal, that the quantitative uncertainties are too great to support identification of a revised standard based specifically on the WREA quantitative estimates of carbon storage benefits to climate. In so doing, she notes that a revised standard, established primarily based on other effects for which our quantitative estimates are less uncertain, can be expected to also provide increased protection in terms of carbon storage.

#### b. Consideration of Visible Foliar Injury

In considering public comments received on the EPA’s consideration of visible foliar injury in its decision on a revised secondary standard, the EPA first notes related advice and comments from the CASAC received during development of the PA. The CASAC stated that “[w]ith respect to the secondary standard, the CASAC concurs with the EPA’s identification of adverse welfare effects related to . . . damage to resource use from foliar injury” (Frey, 2014, p. iii). In its comments on levels of a W126-based standard, the CASAC, seemingly in reference to the WREA visible foliar injury analyses, additionally stated that “[a] level below 10 ppm-hrs is required to reduce foliar injury” (Frey, 2014, pp. iii and 15), with “W126 values below 10 ppm-hr required to reduce the number of sites showing visible foliar injury” (Frey, 2014, p. 14).

Public comments were generally split between two views, either that visible foliar injury was not appropriate to consider in decisions regarding the standard, based on variously identified reasons, or that it should be considered and it would lead the EPA to focus on a W126 value below approximately 10 ppm-hrs. Comments of the former type are discussed in section IV.B.2 above, with, in some cases, additional detail in the Response to Comments document. Commenters expressing the latter view variously cite CASAC advice and figures from the WREA cumulative analysis of USFS biosite data with WREA W126 index value estimates. The EPA disagrees that only a reduction in cumulative exposures to W126 index values below 10 ppm-hrs will affect the occurrence or extent of visible foliar injury. In so doing, we note that the

extensive evidence, which is summarized in the ISA (including studies of the USFS biomonitoring program), analyses in the 2007 Staff Paper and also observations based on the WREA dataset do not support this conclusion.

The evidence regarding visible foliar injury as an indicator of O<sub>3</sub> exposure is well established and generally documents a greater extent and severity of visible foliar injury with higher O<sub>3</sub> exposures and a modifying role of soil moisture conditions (U.S. EPA, 2013, section 9.4.2). As stated in the ISA, “[v]isible foliar injury resulting from exposure to O<sub>3</sub> has been well characterized and documented over several decades of research on many tree, shrub, herbaceous and crop species” and “[o]zone-induced visible foliar injury symptoms on certain bioindicator plant species are considered diagnostic as they have been verified experimentally” (U.S. EPA, 2013, p. 9–41). Further, a recent study highlighted in the ISA, which analyzed trends in the incidence and severity of foliar injury, reported a declining trend in the incidence of foliar injury as peak O<sub>3</sub> concentrations declined (U.S. EPA, 2013, p. 9–40; Smith, 2012). Another study available in this review that focused on O<sub>3</sub>-induced visible foliar injury in forests of west coast states observed that both percentage of biosites with injury and average biosite index were higher for sites with average cumulative O<sub>3</sub> concentrations above 25 ppm-hrs in terms of SUM06 (may correspond to W126 of approximately 21 ppm-hrs [U.S. EPA, 2007, p. 8–26, Appendix 7B]) as compared to groups of sites with lower average cumulative exposure concentrations, with much less clear differences between the two lower exposure groups (Campbell et al., 2007, Figures 27 and 28 and p. 30). A similar finding was reported on the 2007 Staff Paper which reported on an analysis that showed a smaller percentage of injured sites among the group of sites with O<sub>3</sub> exposures below a SUM06 metric of 15 ppm-hrs or a fourth-high metric of 74 ppb as compared to larger groups that also included sites with SUM06 values up to 25 ppm-hrs or fourth-high metric up to 84 ppb, respectively (U.S. EPA 2007, pp. 7–63 to 7–64).

With regard to the comments referencing the WREA cumulative analysis of USFS FHM/FIA biosite data or related CASAC comments, we note some clarification of this analysis. This analysis does not show, as implied by the comments, that at W126 index values above 10 ppm-hrs, there is little change with increasing W126 index in

<sup>200</sup> The report of the 1996 workshop provides no more 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).

the proportion of records with any visible foliar injury (biosite index above 0). As the analysis is a cumulative analysis, each point graphed in the analysis includes the records for the same and lower W126 index values, so the analysis does not compare results for groups of records with differing, non-overlapping W126 index values. Rather, the points represent groups with records (and W126 index values) in common and the number of records in the groups is greater for higher W126 index values (U.S. EPA, 2014b, section 7.2). Additionally, we note that the pattern observed in the cumulative analysis is substantially influenced by the large number of records for which the W126 index estimates are at or below 11 ppm-hrs, more than two thirds of the dataset (Smith and Murphy, 2015, Table 1).

To more fully address the comments related to this WREA analysis, we have drawn several additional observations from the WREA dataset, re-presenting the same data in a different format in a technical memorandum to the docket (Smith and Murphy, 2015). Contrary to the implication of the statements from the commenters and CASAC that no reduction in the occurrence of visible foliar injury can be achieved with exposures above 10 ppm-hrs, both the proportion of records with injury and the average biosite index are lower for groups of records with W126 index estimates at or below 17 ppm-hrs compared to the group for the highest W126 index range. This is true when considered regardless of soil moisture conditions (all records), as well as for dry, normal and wet records, separately (Smith and Murphy, 2015, Table 2). The pattern of the two measures across record groups with lower W126 index values differs with moisture level, with the wetter than normal records generally showing decreasing proportions of injured sites and decreasing average biosite index with lower W126 index values, while little difference in these measures is seen among the middle W126 values although they are lower than the highest W126 index group and higher than the lowest W126 index group (Smith and Murphy, 2015, Table 2). In summary, the EPA disagrees with commenters, noting that the available information, including additional observations from the WREA dataset, indicate declines in the occurrence of visible foliar injury across decreasing W126 index values that are higher than 10 ppm-hrs.

#### c. Use of W126 Metric in Evaluating Vegetation Effects and Public Welfare Protection

In considering public comments received on the EPA's use of the W126 exposure index in its decision on a revised secondary standard, the EPA first notes related advice and comments from the CASAC received during development of the PA. Although we recognize that CASAC's comments on the W126 index were provided in the context of its recommendation for a secondary standard of that form, we find them to also relate to our use of the W126 metric in evaluating the magnitude and extent of vegetation effects that might be expected and conversely the level of protection that might be provided under different air quality conditions. In comments on the first draft PA, the CASAC stated that "discussions and conclusions on biologically relevant exposure metrics are clear and compelling and the focus on the W126 form is appropriate" (Frey and Samet, 2012a). With regard to specific aspects of the W126 index, the CASAC concurred with the second draft PA focus on "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).

The CASAC advice on levels of the W126 index on which to focus for public welfare protection recommended a level within the range of 7 ppm-hrs to 15 ppm-hrs (Frey, 2014c, p. iii). We note, however, as summarized in section IV.E.3 of the proposal, that this advice was provided in the context of the CASAC review of the second draft PA, which concluded that a range from 7 to 17 ppm-hrs was appropriate to consider. In considering the upper end of this range, the CASAC consulted Table 6–1 of the second draft PA which indicated for a W126 index value of 17 ppm-hrs an RBL estimate of 6%, a magnitude that CASAC described as "unacceptably high" and that contributed to a lack CASAC support for W126 exposures values higher than 15 ppm-hrs (Frey, 2014c, p. 14; U.S. EPA 2014d, Table 6–1). As noted in section IV.E.3 of the proposal, revisions to the RBL estimate table in the final PA, which were made in consideration of other CASAC comments, have resulted in changes to the median species RBL estimate associated with each W126 index value, such that the median species RBL estimate for a W126 index value of 17 ppm-hrs in this table in the final PA was 5.3%, rather than the "unacceptably high" value of 6% (U.S.

EPA, 2014c, Table 6–1; U.S. EPA, 2014d, Table 6–1; Frey, 2014c, p. 14).<sup>201</sup> Additionally, the CASAC recognized that the Administrator may, as a policy matter, prefer to use a 3-year average, and stated that in that case, the range of levels should be revised downward (Frey, 2014c, p. iii–iv).

The majority of comments on the W126 index concurred with its use for assessing O<sub>3</sub> exposures, while some commenters additionally expressed the view that this index should be used as the form of the secondary standard (as discussed in section IV.C.2.d below). Most submissions from state and local environmental agencies or governments, as well as organizations of state agencies, that provided comments on the magnitude of cumulative exposure, in terms of the W126 index, appropriate to consider for a revised secondary standard, recommended that the EPA focus on an index value within the EPA's proposed range of 13 to 17 ppm-hrs, as did the industry commenters. These commenters variously noted their agreement with the rationale provided by the EPA in the proposal or cited to CASAC comments, including for a downward adjustment of its recommended values if a 3-year average W126 was used rather than a single year index. Some other commenters, including two groups of environmental organizations, submitted comments recommending a focus on a W126 index level as low as 7 ppm-hrs based on reasons generally focused on consideration of visible foliar injury.

Some aspects of these comments have been addressed in sections IV.C.2.a and IV.C.2.b above. In the Response to Comments document, we have additionally addressed other comments that recommend a focus on W126 index values for specific reasons other than generally citing the CASAC recommended range. Further, in her consideration of a target level of protection for the revised secondary standard in section IV.C.3 below, the Administrator has considered comments from the CASAC regarding the basis for their recommended range.

An additional comment from an organization of western state air quality managers indicated a concern with the use of W126 for vegetation in arid and high altitude regions, such as those in the western states, which the

<sup>201</sup> We additionally note that the median species RBL estimate for 17 ppm-hrs in the final PA is nearly identical to the estimate for 15 ppm-hrs (the value corresponding to the upper end of the CASAC-identified range) that was in the second draft PA (5.2%) which was the subject of the CASAC review (U.S. EPA, 2014c, Table 6–1; U.S. EPA, 2014d, Table 6–1).



commenter hypothesized may have reduced sensitivity. The commenters did not provide evidence of this hypothesis, calling for further research in order to characterize the sensitivity of vegetation in such areas. The EPA agrees that additional research would be useful in more completely characterizing the response of species in such areas, as well as other less well studied areas, but does not find support in the currently available evidence for the commenter's suggestion that species in arid and high altitude regions may be less sensitive than those in other areas.<sup>202</sup>

Among the small number of commenters recommending against using the W126 metric to assess O<sub>3</sub> exposure, a few expressed the view that some other, not-yet-identified cumulative exposure metric should be used. These commenters cited a variety of concerns that they state are not addressed by the W126 index: that plant exposure to and uptake of O<sub>3</sub> are not always equivalent because of variations in stomatal conductance and plant defenses and their respective diel patterns, which will also influence plant response; that the duration between harmful O<sub>3</sub> exposures affects the plant's ability to repair damage; and, that nighttime exposures may be important. These commenters do not identify an alternative to the W126 index that they conclude to better represent exposures relevant to considering O<sub>3</sub> effects on vegetation and particularly for growth effects. The EPA has considered the items raised by these commenters, recognizing some as areas of uncertainty (U.S. EPA, 2013, pp. 9–109 to 9–113), yet has concluded that based on the information available at this time, exposure indices that cumulate and differentially weight the higher hourly average concentrations while also including the “mid-level” values offer the most appropriate approach for use in developing response functions and comparing studies of O<sub>3</sub> effects on vegetation (U.S. EPA, 2013, p. 9–117). When considering the response of vegetation to O<sub>3</sub> exposures represented by the threshold (*e.g.*, SUM06) and non-threshold (*e.g.*, W126) indices, the ISA notes that “the W126 metric does not have a cut-off in the weighting scheme as does SUM06 and thus it includes consideration of potentially damaging exposures below 60 ppb” and that “[t]he

W126 metric also adds increasing weight to hourly concentrations from about 40 ppb to about 100 ppb” (U.S. EPA, 2013, p. 9–104). This aspect of W126 is one way it differs from cut-off metrics such as the SUM06 where all concentrations above 60 ppb are treated equally and is identified by the ISA as “an important feature of the W126 since 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, 2013, p. 9–104). Further, we note the concurrence by CASAC with the EPA's focus on the W126 exposure index, as noted above.

Some commenters also raised concerns regarding the sensitivity of vegetation in desert areas where plants take in ambient air during nighttime rather than daylight hours, such that little exposure occurs from 8 a.m. to 8 p.m., stating that the W126 index as defined by the EPA to cumulate hourly O<sub>3</sub> from 8 a.m. to 8 p.m. may result in an overly stringent exposure level in areas with such vegetation. The EPA recognizes that plants, such as cacti, that commonly occur in desert systems exhibit a particular type of metabolism (referred to as CAM photosynthesis) such that they only open their stomata at night (U.S. EPA, 2013, p. 9–109). We note, however, that few if any O<sub>3</sub> exposure studies of these species are available<sup>203</sup> to further inform our characterization of these species' responses to O<sub>3</sub>, and we have no basis on which to conclude that an exposure level based on the studied species and a daylight exposure metric would be overly or underly stringent in areas where only species utilizing CAM photosynthesis occur. As summarized above, the CASAC advice concurred with the use of an 8am to 8pm diurnal period for the W126 exposure index. Thus, we conclude that for our purposes in this review the focus on daylight hours is appropriate. Our use of the W126 index in this review has been for purposes of characterizing the potential harm and conversely the potential protection that might be afforded from the well-characterized effects of O<sub>3</sub> on vegetation, while recognizing associated uncertainties and limitations. We note that different ecosystems across the U.S. will be expected to be of varying sensitivities with regard to the effects of O<sub>3</sub>. For example, large water bodies without vegetation extending above the water's surface would be expected to be less sensitive than forests of sensitive

species. The EPA notes, however, that the NAAQS are set with applicability to all ambient air in the U.S., such that the secondary O<sub>3</sub> standard provides protection in areas across the U.S. regardless of site-specific aspects of vegetation sensitivity to O<sub>3</sub>. In considering the evidence on O<sub>3</sub> and associated welfare effects, we recognize variability in sensitivity that may relate to a number of factors, as discussed in the ISA (U.S. EPA, 2013, section 9.4.8). This variability is among the Administrator's considerations in setting the secondary standard for O<sub>3</sub> that is requisite to protect public welfare against anticipated or known adverse effects.

Further, some commenters who agreed with a focus on the W126 exposure index also stated that the EPA's definition of the index for the daylight hours of 8 a.m. to 8 p.m. and a 3-month period was not appropriate, stating that derivation of the W126 metric should involve summing concentrations for all 24 hours in each day and all months in each year to avoid underestimating O<sub>3</sub> exposure that the commenters viewed as pertinent. Support for the EPA's definition of the W126 index, with which CASAC concurred (Frey, 2014c, p. iii), is based on the assessment of the evidence in the ISA (U.S. EPA, 2013, section 9.5.3.2) and the context for use of the W126 index in relating O<sub>3</sub> exposure to magnitude and/or extent of O<sub>3</sub> response. This context has a particular focus on growth effects for the purposes of judging the potential for public welfare impacts, as well as the level of protection, associated with different exposure circumstances. We note that the ISA stated there is a lack of information that would allow consideration of the extent to which nocturnal exposures that may be of interest occur (U.S. EPA, 2013, p. 9–109). Additionally, in our use of the W126 index, we are relying on E–R functions based on studies that were generally of 3-month duration and involved controlled exposures during the daylight period. Accordingly we have relied on the E–R function derived for 12-hour and 3-month W126 indices, as described in section IV.A.1 above. To apply these E–R functions to the W126 estimates derived using 24 hours-per-day index values would inaccurately represent the response observed in the study (producing an overestimate). Similarly, with regard to the 3-month duration, “[d]espite the possibility that plants may be exposed to ambient O<sub>3</sub> longer than 3 months in some locations, there is generally a lack of exposure experiments conducted for longer than

<sup>202</sup> For example, we note that among the 11 species for which robust E–R functions have been established for O<sub>3</sub> effects on tree seedling growth, the sensitivity of ponderosa pine, a species occurring in arid and high altitude regions of the western U.S., is similar to the median (U.S. EPA, 2014c, Table 5C–1).

<sup>203</sup> No O<sub>3</sub> exposure studies on cacti or other species that utilize CAM photosynthesis are reported in the ISA (U.S. EPA, 2013).

3 months” (U.S. EPA, 2014c, p. 9–112). Thus, in consideration of the lack of support in the current evidence for characterizing exposure for purposes of estimating RBL based on cumulative exposures derived from a combination of daytime and nighttime exposures and consideration of year-round O<sub>3</sub> concentrations across the U.S., we disagree with the commenters’ view of the appropriateness of using an exposure index based on 24-hour, year-round O<sub>3</sub> concentrations.

The commenters supporting the use of the W126 exposure index were divided with regard to whether the EPA should focus on an annual index or one averaged over three years. Some of the commenters indicating support for the EPA’s proposed focus on a 3-year average W126 index stated that this was appropriate in light of the wide variations in W126 index values that can occur on a year-to-year basis as a result of the natural variation of climatic conditions that have a direct impact on O<sub>3</sub> formation; in their view, these factors are mitigated by use of a 3-yr average, which thus provides “stability” in the assessment dampening out the natural variation of climatic conditions that have a direct impact on O<sub>3</sub> formation. Others noted that use of a 3-year average may be supported as matter of policy. We generally concur with the relevance of these points, among others, to a focus on the 3-year average W126. Other commenters expressed the view that the EPA should focus on an annual W126 index, generally making these comments in the context of expressing their support for a secondary standard with a W126 form. These commenters variously cited CASAC advice and its rationale for preferring a single year W126 form, stated that vegetation damage occurs on an annual basis, and/or questioned the EPA’s statements of greater confidence in conclusions as to O<sub>3</sub> impacts based on a 3-year average exposure metric.

The EPA agrees with commenters that, as discussed in the PA and the proposal, depending on the exposure conditions, O<sub>3</sub> can contribute to measurable effects on vegetation in a single year. We additionally recognize that, as described in the PA and proposal, there is generally a greater significance for effects associated with multiple-year exposures. The proposal described a number of considerations raised in the PA as influencing the Administrator’s decision to focus on a 3-year average W126 index (79 FR 75347, December 17, 2014). These included, among others, the observation of a greater significance for effects associated with multiple-year exposures, and the

uncertainties associated with consideration of annual effects relative to multiple-year effects.

Further, we note that among the judgments contributing to the Administrator’s decision on the level of protection appropriate for the secondary standard are judgments regarding the weight to place on the evidence of specific vegetation-related effects estimated to result across a range of cumulative seasonal concentration-weighted O<sub>3</sub> exposures and judgments on the extent to which such effects in such areas may be considered adverse to public welfare (79 FR 75312, December 17, 2014). Thus, conclusions regarding the extent to which the size and/or prevalence of effects on vegetation in a single year and any ramifications for future years represent an adverse effect to the public welfare, conclusions that are also inherently linked to overall magnitudes of exposures, are dependent on the Administrator’s judgment. Accordingly, the decision regarding the need to focus on a 1-year or 3-year W126 index value is also a judgment of the Administrator, informed by the evidence, staff evaluations and advice from CASAC, as described in section IV.C.3 below.

#### d. Form and Averaging Time

In considering comments received on the proposed form for the revised standard, the EPA first notes the advice and comments from the CASAC, received in its review of the second draft PA. Similar to its advice in the last review, the CASAC recommended “establishing a revised form of the secondary standard to be the biologically relevant W126 index” (Frey, 2014c, p. iii). With regard to its reasons for this view, the CASAC cites the PA in stating that it “concur[s] with the justification in [section 5.7] that the form of the standard should be changed from the current 8-hr form to the cumulative W126 index” (Frey, 2014c, p. 12). In addressing specific aspects of this index, the CASAC concurred with the EPA’s focus on the 3-month period with the highest index value and further states that “[a]ccumulation over the 08:00 a.m.–08:00 p.m. daytime 12-hour period is a scientifically acceptable and recommended means of generalizing across latitudes and seasons” (Frey, 2014c, p. 13). As section 5.7 of the PA discusses the W126 index in the context of the support in the evidence for use of the W126 exposure index for assessing impacts of O<sub>3</sub> on vegetation and the extent of protection from such impacts, we interpret CASAC’s statement on this point to indicate that the basis for CASAC’s view with regard to the form

for the secondary standard relates to the appropriateness of the W126 exposure index for those assessment purposes.<sup>204</sup> <sup>205</sup>

The public comments on the form for a revised secondary standard were divided. Most of the state and local environmental agencies or governments, and all of the tribal agencies and organizations that provided comments on the form for the secondary standard concurred with the EPA’s proposed decision, as did the industry commenters. These commenters generally indicated agreement with the rationale provided in the proposal that drew from the EPA analyses of recent air quality data examining relationships at sites across the U.S. between values of the fourth-high metric (the current design value) and values of a 3-year average W126-based metric, stating that this analysis showed that a standard in the form of the fourth-high metric, as proposed, can provide air quality consistent with or below the range of 3-year W126 exposure index values identified in the proposal. Some commenters additionally stated that the choice of form was a policy decision for the EPA and that little or no additional protection of public welfare would be gained by adopting a W126-based form. Some of these commenters provided analyses of data for their state or region that further supported this view. As

<sup>204</sup> Section 5.7 of the PA states that “the evidence continues to provide a strong basis for concluding that it is appropriate to judge impacts of O<sub>3</sub> 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,” references the support of CASAC for a W126-based secondary standard, and then concludes that “based on the consistent and well-established evidence described above, . . . the most appropriate and biologically relevant way to relate O<sub>3</sub> exposure to plant growth, and to determine what would be adequate protection for public welfare effects attributable to the presence of O<sub>3</sub> in the ambient air, is to characterize exposures in terms of a cumulative seasonal form, and in particular the W126 metric” (U.S. EPA, 2014c, p. 5–78).

<sup>205</sup> The CASAC also mentioned its support for revising the secondary standard to a W126 index-based form in its review of Chapter 6 of the second draft PA (Frey, 2014c, p. 13). Similar to section 5.7, in that chapter of the PA staff concluded that “specific features associated with the W126 index still make it the most appropriate and biologically relevant cumulative concentration-weighted form for use in the context of the secondary O<sub>3</sub> NAAQS review” (U.S. EPA, 2014c, p. 6–5) and also concluded that “it is appropriate to consider a revised secondary standard in terms of the cumulative, seasonal, concentration-weighted form, the W126 index” (U.S. EPA, 2014c, p. 6–57).

<sup>206</sup> The term design value is commonly used to refer to the metric for the standard. Consistent with the summary in section I.D above, a design value is the statistic that describes the air quality of a given location in terms of the indicator, form and averaging time of the standard such that it can then be compared to the level of the standard.

described in section IV.C.3 below, the EPA generally agrees with these commenters.

Some commenters, including a regional organization of state agencies and two groups of environmental organizations, submitted comments recommending revision of the standard to a cumulative, seasonal form based on the W126 index. In support of their position, these commenters generally cited CASAC advice, variously additionally indicating their view that the standard form should be a metric described as biologically relevant, and that the existing form, with a level in the proposed range, would not provide adequate ecosystem protection. Some commenters additionally suggested that the EPA cannot lawfully retain the form and averaging time that were initially established for purposes of the primary standard when the EPA has identified the W126 index as a metric appropriate for judging vegetation-related effects on public welfare. With regard to the EPA air quality analyses, summarized in the proposal, of the W126 index values at sites where O<sub>3</sub> concentrations met different levels of fourth-high metric, some of these commenters stated that the analyses showed widespread variation in W126 values for each fourth-high metric examined. Further, some commenters disagreed with the EPA that the analyses indicated that a revised standard level within the proposed range would be expected to limit W126 exposures in the future to the extent suggested by the analyses of data from the past.

We agree with public commenters and CASAC regarding the appropriateness of the W126 index (the sum of hourly concentrations over a specified period) as a biologically relevant metric for assessing exposures of concern for vegetation-related public welfare effects, as discussed in the proposal, PA and ISA. Accordingly, we agree that this metric is appropriate for use in considering the protection that might be expected to be afforded by potential alternative secondary standards, as discussed in section IV.C.2.c above. We disagree with commenters, however, that use of the W126 metric for this purpose dictates that we must establish a secondary standard with a W126 index form.

In support of this position, we note the common use, in assessments conducted for NAAQS reviews, of exposure metrics that differ in a variety of ways from the ambient air concentration metrics of those

standards.<sup>206</sup> Across reviews for the various NAAQS pollutants, we have used a variety of exposure metrics to evaluate the protection afforded by the standards. These exposure metrics are based on the health or welfare effects evidence for the specific pollutant and commonly, in assessments for primary standards, on established exposure-response relationships or health-based benchmarks (doses or exposures of concern) for effects associated with specific exposure circumstances. Some examples of exposure metrics used to evaluate health impacts in primary standard reviews include the concentration of lead in blood of young children and a 5-minute exposure concentration for sulfur dioxide. In contrast, the health-based standards for these two pollutants are the 3-month concentration of lead in total suspended particles and the average across three years of the 99th percentile of 1-hour daily maximum concentration of sulfur dioxide in ambient air, respectively (73 FR 66964, November 12, 2008; 75 FR 35520, June 22, 2010). In somewhat similar manner, in the 2012 PM review, the EPA assessed the extent to which the existing 24-hour secondary standard for PM<sub>2.5</sub>, expressed as a 24-hour concentration (of PM<sub>2.5</sub> mass per cubic meter of air) not to be exceeded more than once per year on average over three years, could provide the desired protection from effects on visibility in terms of the 90th percentile, 24-hour average PM<sub>2.5</sub> light extinction, averaged over three years, based on speciated PM<sub>2.5</sub> mass concentrations and relative humidity data (79 FR 3086, January 15, 2013). Additionally, in the case of the screening-level risk analyses in the 2008 review of the secondary standard for lead, concentrations of lead in soil, surface water and sediment were evaluated to assess the potential for welfare effects related to lead deposition from air, while the standard is expressed in terms of the concentration of lead in particles suspended in air (73 FR 67009, November 12, 2008).

Further, depending on the evidence base, some NAAQS reviews may consider multiple exposure metrics in assessing risks associated with a particular pollutant in ambient air in order to judge the adequacy of an existing standard in providing the required level of protection. And a standard with an averaging time of one

<sup>206</sup>The term design value is commonly used to refer to the metric for the standard. Consistent with the summary in section I.D above, a design value is the statistic that describes the air quality of a given location in terms of the indicator, form and averaging time of the standard such that it can then be compared to the level of the standard.

duration may provide protection against effects elicited by exposures of appreciably shorter or longer durations. For example, in the current review of the primary O<sub>3</sub> standard, as described in section II above, we have considered the potential for effects associated with both short- and long-term exposures and concluded, based on a combination of air quality and risk analyses and the health effects evidence, that the existing standard with its short (8-hour) averaging time provides control of both the long and short term exposures (*e.g.*, from one hour to months or years) that may be of concern to public health. Similarly, during the 1996 review of the NO<sub>2</sub> primary standard, while health effects were recognized to result from both long-term and short-term exposures to NO<sub>2</sub>, the primary standard, which was a long-term (annual) standard, was concluded to provide the requisite protection against both long- and short-term exposures (61 FR 52852, Oct 8 1996). In the subsequent review of the NO<sub>2</sub> primary standard in which the available air quality information indicated that the annual standard was not providing the needed control of the shorter term exposures, an additional short-term standard was established (75 FR 6474, February 9, 2010).

Thus, we note that different metrics may logically, reasonably, and for technically sound reasons, be used in assessing exposures of concern or characterizing risk as compared to the metric of the standard which is used to control air quality to provide the desired degree of protection. That is, exposure metrics are used to assess the likely occurrence and/or frequency and extent of effects under different air quality conditions, while the air quality standards are intended to control air quality to the extent requisite to protect from the occurrence of public health or welfare effects judged to be adverse. In this review of the secondary standard for O<sub>3</sub>, the EPA agrees that, for the reasons summarized in section IV.A.1 above and described in the ISA, the W126 index—and not an 8-hour daily maximum concentration that has relevance in human health risk characterization, as described in section II above—is the appropriate metric for assessing exposures of concern for vegetation, characterizing risk to public welfare, and evaluating what air quality conditions might provide the desired degree of public welfare protection. We disagree, however, that the secondary standard must be established using that same metric.

Moreover, we note that the CAA does not require that the secondary O<sub>3</sub> standard be established in a specific

form. Section 109(b)(2) provides only that any secondary NAAQS “shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria, 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. . . . [S]econdary standards may be revised in the same manner as promulgated.” The EPA interprets this provision to leave it considerable discretion to determine whether a particular form is appropriate, in combination with the other aspects of the standard (averaging time, level and indicator), for specifying the air quality that provides the requisite protection, and to determine whether, once a standard has been established in a particular form, that form must be revised. Moreover, nothing in the Act or the relevant case law precludes the EPA from establishing a secondary standard equivalent to the primary standard in some or all respects, as long as the Agency has engaged in reasoned decision-making.<sup>207</sup>

With regard to the commenter’s emphasis on advice from CASAC on the form of the secondary standard, the EPA agrees with the importance of giving such advice careful consideration. The EPA further notes, however, that the Administrator is not legally precluded from departing from CASAC’s recommendations, when she has provided an explanation of the reasons for such differences.<sup>208</sup> Accordingly, in reaching conclusions on the revised secondary standard in this review, the Administrator has given careful consideration to the CASAC advice in this review and, when she has differed from CASAC recommendations, she has fully explained the reasons and judgments that led her to a different conclusion, as described in section IV.C.3 below.

In disagreeing with the EPA’s conclusions drawn from analyses of recent air quality data on the extent to which cumulative seasonal exposures might be limited to within or below the identified 3-year average W126 index values by controlling air quality using different values for the fourth-high

metric, one group of environmental organizations emphasized the range of W126 index values that occur at monitors with concentrations at or below specific values for the fourth-high metric. For monitor observations for which the fourth-high metric was at or below 70 ppb, this commenter group stated that some sites have 3-year average W126 index values above 17 ppm-hrs and noted a maximum 3-year W126 index value of 19.1 ppm-hrs, while additionally noting occurrences of other W126 values above the CASAC range of 7 to 15 ppm-hrs. This commenter additionally stated that the air quality data “do not support a claim of congruence” between the fourth-high and W126 metrics (e.g., ALA et al., p. 196), that there is no basis for concluding that there is some fundamental underlying relationship that assures meeting the fourth-high metric will mean meeting any of the W126 options, and that the relationship between the metrics is non-linear with significant spread in the data (citing visual inspection of a graph).

The EPA does not agree with the commenter’s statements regarding the relationship between the two metrics.<sup>209</sup> We have not, as stated by the commenter, claimed there to be “congruence” between the two metrics (e.g., ALA et al., p. 196), or that the two metrics coincide exactly. Rather, at any location, values of both metrics are a reflection of the temporal distribution of hourly O<sub>3</sub> concentrations across the year and both vary in response to changes in that distribution. While the EPA’s air quality analysis shows that the specific relationship differs among individual sites, it documents an overall strong, positive, non-linear relationship between the two metrics (Wells, 2014a, p. 6, Figures 5a and 5b; Wells, 2015b). Further, this analysis finds the amount of year-to-year variability in the two metrics tended to decrease over time with decreasing O<sub>3</sub> concentrations, especially for the W126 metric, as described in section IV.E.4 of the proposal (Wells, 2014a; Wells, 2015b).

With regard to the highest 3-year average W126 exposure index values that might reasonably be expected in the future in areas where a revised standard with a fourth-high form is met, we disagree with the commenters as to the

significance of the W126 index value of 19.1 ppm-hrs in the 13-year dataset. This value, for a site during the period 2006–2008, is the only occurrence at or above 19 ppm-hrs in the nearly 4000 3-year W126 index values—across the 11 3-year periods extending back in time from 2013—for which the fourth-high metric for the same monitor location is at or below 70 ppb. This is clearly an isolated occurrence.

In considering this comment, we have expanded the technical memorandum that was available at the time of proposal (Wells, 2014a). The expanded memorandum describes the same air quality analyses for 3-year periods from 2001 through 2013 as the 2014 memorandum, and includes additional summary tables for all 3-year periods from 2001 through 2013 as well as tables for the most recent period, 2011–2013 (Wells, 2015b). After the 3-year W126 index value of 19 ppm-hrs, the next three highest 3-year average W126 index values, which are the only other such values above 17 ppm-hrs in the 13-year dataset, and which also occur during periods in the past, round to 18 ppm-hrs (Wells, 2015b). Additionally, we note that reductions in the fourth-high metric over the 13-year period analyzed are strongly associated with reductions in the cumulative W126 index (Wells, 2014a, Figure 11, Table 6; Wells, 2015b). Specifically, the regression analysis of changes in W126 index between the 2001–2003 period and the 2011–2013 period with changes in the fourth-high metric across the same periods indicates a fairly linear and positive relationship between reductions of the two types of metrics, with, on average, a change of approximately 0.7 ppm-hr in the W126 index per ppb change in the fourth-high metric value. From this information we conclude that W126 exposures above 17 ppm-hrs at sites for which the fourth-high metric is at or below 70 ppb would be expected to continue to be rare in the future, particularly as steps are taken to meet a 70 ppb standard.

With regard to the comment that the relationship between the two metrics varies across locations, the EPA agrees that there is variation in cumulative seasonal O<sub>3</sub> exposure (in terms of a 3-year average W126 index) among locations that are at or below the same fourth-high metric. As noted in the proposal, the analysis illustrates this variation, with the locations in the West and Southwest NOAA climatic regions tending to have the highest cumulative seasonal exposures for the same fourth-high metric value. In considering expectations for the future in light of this observation, however, we note that

<sup>207</sup> In fact, the D.C. Circuit has upheld secondary NAAQS that were identical to the corresponding primary standard for the pollutant (e.g., *ATA III*, 283 F.3d at 375, 380 [D.C. Cir. 2002, upholding secondary standards for PM<sub>2.5</sub> and O<sub>3</sub> that were identical to primary standards]).

<sup>208</sup> See CAA sections 307(d)(3) and 307(d)(6)(A); see also *Mississippi v. EPA*, 744 F.3d 1334, 1354 (D.C. Cir. 2013) (“Although EPA is not bound by CASAC’s recommendations, it must fully explain its reasons for any departure from them”).

<sup>209</sup> The EPA additionally notes that commenters contradict their own assertion when, after stating their view that no relationship exists between the 4th high and W126 metrics, the commenter then states that there is a nonlinear relationship and yet then relies on a predicted *linear* relationship to estimate W126 values occurring when air quality meets different values for the 4th high metric at 11 national parks.

the regional regressions of reductions in W126 metric with reductions in the fourth-high metric indicate that the Southwest and West regions, which had the greatest potential for sites having 3-year W126 index values greater than the various W126 values of interest when fourth-high values are less than or equal to the various fourth-high metric values of interest, also exhibited the greatest reduction in the W126 index values per unit reduction in the fourth-high values (Wells, 2015b). Thus, in considering the potential for occurrences of values above 17 ppm-hrs in the future in areas that meet a fourth-high of 70 ppb, the EPA notes that the analysis indicates that those areas that exhibited the greatest likelihood of occurrence of a 3-year W126 index above a level of interest (e.g., the commenters' example in the Southwest region of a value of 19.1 ppm-hrs [2006–2008] in comparison to the W126 level of 17 ppm-hrs) also exhibit the greatest improvement in W126 per unit decrease in fourth-high metric.<sup>210</sup> It is expected that future control programs designed to meet a standard with a fourth-high form would provide similar improvements in terms of the W126 metric.

As part of their rationale in support of revising the current form and averaging time, one commenter pointed to the regional variation in the highest W126 index values expected at sites that just meet a fourth-high metric of 70 ppb, based on the EPA's analysis of recent air quality data available at the time of the proposal (Wells, 2014a). This commenter observed that, while in some U.S. regions, locations that meet a potential alternative standard with the current form and a level of 70 ppb also have 3-year average W126 index values no higher than 17 ppm-hrs, the highest W126 index values in other parts of the country are lower. As a result, the commenter concluded that such a standard would result in regionally differing levels of welfare protection. The commenter additionally states that, for extreme values, a W126 form for the secondary standard would also offer different levels of protection, although with the primary standard setting the upper boundary for such values.

The EPA recognizes that a standard with the current form might be expected to result in regionally differing

distributions of W126 exposure index values (including different maximum values) depending on precursor sources, local meteorology, and patterns of O<sub>3</sub> formation. Variation in exposures is to be expected with any standard (secondary or primary) of any form. In fact, variation in exposures and any associated variation in welfare or health risk is generally an inherent aspect of the Administrator's judgment on a specific standard, and any associated variation in welfare or health protection may play a role in the Administrator's judgment with regard to public welfare or public health protection objectives for a national standard. In considering the comment, however, we have focused only on the extent to which the commenter's conclusion that a secondary standard of the current form and averaging time would provide regionally varying welfare protection might indicate that the specified air quality is more (or less) than necessary to achieve the purposes of the standard. In so doing, we additionally respond to a separate comment that the EPA needs to address how the revised secondary standard is neither more or less than necessary to protect the public welfare.

The CAA requirement in establishing a standard is that it be set at a level of air quality that is requisite, meaning "sufficient, but not more than necessary" (*Whitman v. American Trucking Ass'n*, 531 U.S. 457, 473 [2001]). We note that the air quality that is specified by the revised primary standard has been concluded to be "necessary" and it may be reasonable and appropriate to consider the stringency of the secondary standard in light of what is identified as "necessary" for the primary standard. The EPA considered the stringency of the O<sub>3</sub> secondary standard in this way in the 1979 decision (44 FR 8211, February 8, 1979), which was upheld in subsequent litigation (*API v. Costle*, 665 F.2d 1176 [D.C. Cir. 1991]). We note that, in similar manner, the commenter considered public welfare protection that might be afforded by the primary standard in noting that the primary standard would be expected to provide welfare protection from extreme values.<sup>211</sup>

<sup>211</sup> As described earlier in this section, the EPA has also considered the air quality specified by one secondary standard in a decision on the need for a second secondary standard. In the decision not to adopt a second PM<sub>2.5</sub> secondary standard specific to visibility-related welfare effects, the Administrator, after describing the public welfare protection objective related to visibility effects, considered analyses that related air quality associated with the existing secondary standard to that expected for the proposed visibility-focused secondary standard. From these analyses, she

In addressing the remand of the 2008 secondary standard in this rulemaking, as discussed in section IV.C.2.e below, the EPA recognizes that it must explain the basis for concluding that the standard selected by the Administrator specifies air quality that will provide the degree of public welfare protection needed from the secondary standard (*Mississippi v. EPA*, 744 F.3d 1334, 1360–61 [D.C. Cir. 2013]). In this review, the Administrator describes the degree or level of public welfare protection needed from the secondary standard and fully explains the basis for concluding that the standard selected specifies air quality that will provide that degree of protection. If the Administrator concludes that the level of air quality specified by the primary standard would provide sufficient protection against known or anticipated adverse public welfare effects, the EPA believes that a secondary standard with that indicator, level, form and averaging time could be considered to be requisite. If the level of air quality that areas will need to achieve or maintain for purposes of the primary standard also provides a level of air quality that is adequate to provide the level of protection identified for the secondary standard, there would be little purpose in requiring the EPA to establish a less stringent secondary standard. For these reasons, the expectation of regionally differing cumulative exposures under a secondary standard of the current form and averaging time does not lead us to conclude that the air quality specified by such a standard would be more (or less) than necessary (and thus not requisite) for the desired level of public welfare protection.

#### e. Revisions to the Standard Level

Some comments specifically addressed the level for a revised secondary standard of the current form and averaging time. Of the comments that addressed this, some from states or industry groups generally supported a level within the proposed range, frequently specifying the upper end of the range (70 ppb), while comments

concluded sufficient protection against visibility effects would be provided by the existing standard, and to the extent that the existing standard would provide more protection than had been her objective for such effects, adoption of a second secondary standard focused on visibility would not change that result (78 FR 3227–3228, January 15, 2013). This decision responded to a court remand of the prior EPA decision that visibility protection would be afforded by a secondary standard set equal to the primary standard based on the court's conclusion that the EPA had not adequately described the Administrator's objectives for visibility-related public welfare protection under the standard (*American Farm Bureau*, 559 F.3d at 530–531).

<sup>210</sup> Additionally, O<sub>3</sub> levels at any location are influenced by upwind precursor emissions, and many rural areas, including the site referenced by the commenter, are impacted by precursor emissions from upwind urban areas, such that as emissions are reduced to meet a revised standard in the upwind locations, reductions in those upwind emissions will contribute to reductions at the downwind sites (Wells, 2014a; ISA, pp. 3–129 to 3–133).

from tribes and tribal organizations, and a few others, recommended a level no higher than 65 ppb. The Administrator has considered such comments in reaching her decision on the appropriate revisions to the standard, described in section IV.C.3. Detailed aspects of these comments are discussed in the Response to Comments document.

#### f. 2013 Court Remand and Levels of Protection

Both industry groups and a group of environmental advocacy organizations submitted comments on the extent to which the proposal addressed the July 2013 remand of the secondary standard by the U.S. Court of Appeals for the D.C. Circuit. The former generally concluded that the proposal had adequately addressed the remand, while the latter expressed the view that the EPA had failed to comply with the court's remand because it had failed to identify the target levels of vegetation protection for which the proposed range of standards would provide the requisite protection, claiming that the identified W126 index range of 13–17 ppm-hrs was not based on a proposed level of protection against biomass loss, carbon storage loss, or foliar injury that the EPA had identified as requisite for public welfare.

We agree with the comments that state that we have addressed the court's remand. More specifically, with this rulemaking, including today's decision and the Administrator's conclusions described in section IV.C.3 below, the EPA has fully addressed the remand of the 2008 secondary O<sub>3</sub> standard. In *Mississippi v. EPA*, the D.C. Circuit remanded the 2008 secondary O<sub>3</sub> standard to the EPA for reconsideration because it had not adequately explained why that standard provided the requisite public welfare protection. 744 F.3d 1334, 1360–61 (D.C. Cir. 2013). In doing so, the court relied on the language of CAA section 109(b)(2), and the court's prior decision, *American Farm Bureau Federation v. EPA*, 559 F.3d 512, 528–32 (D.C. Cir. 2009), which came to the same conclusion for the 2006 secondary PM<sub>2.5</sub> standard. Both decisions recognize that the plain language of section 109(b)(2) requires the EPA to “specify a level of air quality the maintenance of which . . . is requisite to protect the public welfare from any known or anticipated adverse effects” (*Mississippi*, 744 F.3d at 1360 [citing *American Farm Bureau*, 559 F.3d at 530]). Further, explaining that it was insufficient for the EPA “merely to compare the level of protection afforded by the primary standard to possible secondary standards and to find the two

roughly equivalent” (*Mississippi*, 744 F.3d at 1360), the court rejected the EPA's justification for setting the secondary standard equivalent to the primary standard because that justification was based on comparing the protection from the primary standard to that expected from one possible standard with a cumulative, seasonal form (21 ppm-hrs) without stating that such a cumulative seasonal standard would be requisite to protect welfare or explaining why that would be so. Because the EPA had “failed to determine what level of protection was ‘requisite to protect the public welfare’” (*Mississippi*, 744 F.3d at 1362), the court found that the EPA's rationale failed to satisfy the requirements of the Act.

Today's rulemaking both satisfies the requirements of section 109(b)(2) of the Act and addresses the issues raised in the court's remand. In this rulemaking, the Administrator has established a revised secondary standard that replaces the remanded 2008 secondary standard. In so doing, based on her consideration of the currently available evidence and quantitative exposure and air quality information, as well as advice from CASAC and input from public comments, the Administrator has described the requisite public welfare protection for the secondary standard and explained how the standard selected specifies air quality that will provide that protection. As explained in detail in IV.C.3 below, in this review the Administrator is describing the public welfare protection she finds requisite in terms of seedling RBL in the median species, which serves as a surrogate for a broader array of O<sub>3</sub> effects at the plant and ecosystem levels. This description of the desired protection sufficiently articulates the standard that the Administrator is using to evaluate welfare protection. Further, the Administrator has considered air quality analyses in determining how to achieve the air quality conditions associated with the desired protection. Based on these analyses, the Administrator is determining that revising the level of the secondary standard to 70 ppb, while retaining the current form, averaging time, and indicator, specifies a level of air quality that will provide the requisite public welfare protection.

To the extent the comments suggest that the EPA is required in establishing a standard to identify a precise and quantified level of public welfare protection that is requisite with respect to every potentially adverse public welfare impact (e.g., visible foliar injury, crop yield loss) that is considered in establishing the standard, we disagree. While the D.C. Circuit has required the

EPA to “qualitatively describe the standard governing its selection of particular NAAQS,” it has expressly “rejected the notion that the Agency must establish a measure of the risk to safety it considers adequate to protect public health every time it establishes a NAAQS” (*ATA III*, 283 F.3d at 369 [internal marks and citations omitted]). That is, the EPA must “engage in reasoned decision-making,” but is not required to “definitively identify pollutant levels below which risks to public health are negligible” (*ATA III*, 283 F.3d at 370). This principle recognizes that the Act requires the EPA to establish NAAQS even when the risks or effects of a pollutant cannot be quantified or precisely identified because of scientific uncertainty concerning such effects at atmospheric concentrations (*ATA III*, 283 F.3d at 370). Though these decisions specifically address setting a primary standard under CAA section 109(b)(1), we believe the same principles apply to the parallel provision in section 109(b)(2) governing secondary standards. Accordingly, while the EPA recognizes that it must explain the basis for concluding that the standard selected by the Administrator specifies air quality that will provide the protection against adverse effects on public welfare needed from the secondary standard (*Mississippi v. EPA*, 744 F.3d 1334, 1360–61 [D.C. Cir. 2013]), the CAA does not require the EPA to precisely quantify the measure of protection that is necessary to protect the public welfare in establishing a secondary standard. In light of the Administrator's description of the desired public welfare protection in IV.C.3 below, which has both qualitative and quantitative components, the EPA is not required to further reduce this description to a precise, quantitative target level of vegetation protection. Moreover, nothing in the CAA or in case law requires the EPA to identify a target level of protection for any particular public welfare effect, such as vegetation effects, but rather leaves the Administrator discretion in judging how to describe the public welfare protection that she concludes is requisite. In IV.C.3 below, the Administrator explains her reasoning for giving primary focus to growth-related effects in describing the requisite welfare protection, rather than to other welfare effects such as foliar injury, for which there are more uncertainties and less predictability with respect to the severity of the effects that would be expected from varying O<sub>3</sub> exposures in the natural environment

and the significance of the associated impacts to public welfare.

### 3. Administrator's Conclusions on Revision

In reaching her decision on the appropriate revisions to the secondary standard, the Administrator has drawn on (1) the ISA conclusions regarding the weight of the evidence for a range of welfare effects associated with O<sub>3</sub> in ambient air, quantitative findings regarding air quality and ecosystem exposures associated with such effects, and associated limitations and uncertainties; (2) staff evaluations in the PA of the evidence summarized in the ISA, the exposure/risk information developed in the WREA and analyses of air quality monitoring information; (3) additional air quality analyses of relationships between air quality metrics based on form and averaging time of the current standard and the W126 cumulative seasonal exposure index; (4) CASAC advice; and (5) consideration of public comments. After giving careful consideration to all of this information, the Administrator believes that the conclusions and policy judgments supporting her proposed decision remain valid.

The Administrator concludes it is appropriate to continue to use O<sub>3</sub> as the indicator for a secondary standard intended to address adverse effects to public welfare associated with exposure to O<sub>3</sub> alone and in combination with related photochemical oxidants. In this review, no alternatives to O<sub>3</sub> have been advanced as being a more appropriate surrogate for ambient photochemical oxidants. Advice from CASAC concurs with the appropriateness of retaining the current indicator. Thus, as is the case for the primary standard (discussed above in section II.C.1), the Administrator has decided to retain O<sub>3</sub> as the indicator for the secondary standard. In so doing, she recognizes that measures leading to reductions in ecosystem exposures to O<sub>3</sub> would also be expected to reduce exposures to other photochemical oxidants.

In her decision on the other elements of the standard, the Administrator has considered the body of evidence and information in a systematic fashion, giving appropriate consideration to the important findings of the ISA as to the effects of O<sub>3</sub> in ambient air that may present risks to the public welfare, measures of exposure best formulated for assessment of these effects, associated evidence regarding ecosystem exposures and air quality associated with such effects; judgments regarding the weight to place on strengths, limitations and uncertainties

of this full body of information; and public welfare policy judgments on the appropriate degree of protection and the form and level of a revised standard that will provide such protection. In reaching her decision, the Administrator 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 known or anticipated adverse effects. In addition, we note that the elements of the standard (indicator, level, form, and averaging time) are considered together in assessing the protection provided by a new or revised standard, and the EPA's approach for considering the elements of a new or revised standard is part of the exercise of the judgment of the Administrator.

As an initial matter, the Administrator recognizes the robustness of the longstanding evidence, described in the ISA, of O<sub>3</sub> effects on vegetation and associated terrestrial ecosystems. The newly available studies and analyses have strengthened the evidence for the current review that provides the foundation for the Administrator's consideration of O<sub>3</sub> effects, associated public welfare protection objectives, and the revisions to the current standard needed to achieve those objectives. In light of the extensive evidence base in this regard, the Administrator focuses on protection against adverse public welfare effects of O<sub>3</sub> related effects on vegetation. In so doing, she takes note of effects that compromise plant function and productivity, with associated effects on ecosystems. She is particularly concerned about such effects in natural ecosystems, such as those in areas with protection designated by Congress for current and future generations, as well as areas similarly set aside by states, tribes and public interest groups with the intention of providing similar benefits to the public welfare. She additionally recognizes that providing protection for this purpose will also provide a level of protection for other vegetation that is used by the public and potentially affected by O<sub>3</sub> including timber, produce grown for consumption and horticultural plants used for landscaping.

A central issue in this review of the secondary standard, as in the last review (completed in 2008), has been consideration of the role for a cumulative seasonal exposure index. In the last review, the Administrator proposed such an index as one of two options for the form of a revised standard. The Administrator's decision in that review was to retain the existing

form and averaging time, while revising the standard level to provide the desired level of protection. As described in section IV.A above, this decision was remanded to the EPA in 2013 by the DC Circuit. In the current review, the ISA evaluates the evidence and concludes that, among the approaches investigated, quantifying exposure with a cumulative seasonal index best captures the aspects of exposure that relate to effects on vegetation, particularly those related to growth and yield. The PA considered this finding both in the context of assessing potential impacts, and, conversely, the protection from such impacts that might be realized, as well as in the context of using a cumulative seasonal exposure index as a form for the secondary standard. In the proposal, the Administrator focused on the former context, as an exposure index, while additionally soliciting comment on use of the index as the form for the revised standard. Advice from CASAC, all of which was received prior to the proposal, has largely emphasized the latter context, and that was also the focus of some comments.

In considering revisions to the secondary standard that will specify a level of air quality to provide the necessary public welfare protection, the Administrator focuses on use of a cumulative seasonal exposure index, including specifically the W126 index as defined in the proposal, for assessing exposure, both for making judgments with regard to the potential harm to public welfare posed by conditions allowed by various levels of air quality and for making the associated judgments regarding the appropriate degree of protection against such potential harm. In so doing, the Administrator takes note of the conclusions in the ISA and PA, with which the CASAC concurred, that, based on the currently available evidence, a cumulative seasonal concentration-weighted index best captures the aspects of ecosystem exposure to O<sub>3</sub> in ambient air that impact vegetation. In considering the public comments in this area, she notes the broad support for use of such a metric as an exposure index, with many additionally supporting its use as the form for a revised standard, in light of CASAC advice on that point. Thus, based on the substantial support in the evidence and CASAC advice, and in consideration of public comments, the Administrator concludes that it is appropriate to use such a cumulative seasonal concentration-weighted index for purposes of assessing the potential



public welfare risks, and similarly, for assessing the potential protection achieved against such risks on a national scale.

The Administrator has considered conclusions of the ISA and PA, as well as advice from CASAC and public comments, regarding different cumulative, concentration-weighted metrics, and different temporal definitions of aspects of these metrics. The Administrator takes note of the PA conclusions in support of the W126 exposure index, recognized by the ISA for its strength in weighting potentially damaging O<sub>3</sub> concentrations that contributes to the advantages it offers over other weighted cumulative indices. With regard to the relevant definitions for the temporal aspects of this index, conclusions in the ISA and PA, and such considerations in the last review, have led to a focus on a maximum 3-month, 12-hour index, defined by the 3-consecutive-month period within the O<sub>3</sub> season with the maximum sum of W126-weighted hourly O<sub>3</sub> concentrations during the period from 8:00 a.m. to 8:00 p.m. each day (as explained in section IV.A.1.c above). The Administrator takes note of the support in the ISA and PA, as well as CASAC recommendations for consideration of the W126 index defined in this way. While recognizing that no one definition of an exposure metric used for the assessment of protection for multiple effects at a national scale will be exactly tailored to every species or each vegetation type, ecosystem and region of the country, as discussed in section IV.C.2 above, the Administrator judges that on balance, a W126 index derived in this way, and averaged over three years, as discussed below, will be appropriate for such purposes.

In considering the appropriate exposure index to facilitate assessment of the level of protection afforded to the public welfare by alternative secondary standards in the proposal, the Administrator concluded that a 3-year average W126 index was appropriate for these purposes. A number of considerations raised in the PA influenced the Administrator's conclusion at the time of proposal, in combination with public welfare judgments regarding the weight to place on the evidence of specific vegetation-related effects estimated to result across a range of cumulative seasonal concentration-weighted O<sub>3</sub> exposures and judgments on the extent to which such effects in such areas may be considered adverse to public welfare (79 FR 76347, 75312, December 17, 2014.). Some comments were received from the

public on this aspect of the proposed decision, as discussed in section IV.C.2 above, and have been considered in the conclusions reached here.

The Administrator continues to place weight on key aspects raised in the PA and summarized in the proposal on the appropriateness of considering a 3-year average index. The Administrator notes the PA consideration of the potential for multiple consecutive years of critical O<sub>3</sub> exposures to result in larger impacts on forested areas than intermittent occurrences of such exposures due to the potential for compounding effects on tree growth. The Administrator additionally notes the evidence, as considered in the PA and summarized in the proposal, for some perennial species of some effects associated with a single year's exposure of a critical magnitude that may have the potential for some "carry over" of effects on plant growth or reproduction in the subsequent season. Further, the Administrator notes the occurrence of visible foliar injury and growth or yield loss in annual plants or crops associated with exposures of a critical magnitude. While the Administrator appreciates that the scientific evidence documents the effects on vegetation resulting from individual growing season exposures of specific magnitude, including those that can affect the vegetation in subsequent years, she is also mindful, both of the strengths and limitations of the evidence, and of the information on which to base her judgments with regard to adversity of effects on the public welfare. The Administrator also recognizes uncertainties associated with interpretation of the public welfare significance of effects resulting from a single-year exposure, and that the public welfare significance of effects associated with multiple years of critical exposures are potentially greater than those associated with a single year of such exposure.

As she did for the proposal, the Administrator has considered advice from CASAC in this area, including the CASAC comments that it favors a W126-based secondary standard with a single year form, that its recommended range of levels relates to such a form, and that a lower range (e.g., with 13 ppm-hrs at the upper end) would pertain to a 3-year form. The Administrator also notes CASAC's recognition that her decision on use of a 3-year average over a single-year W126 index may be a matter of policy. While recognizing the potential for effects on vegetation associated with a single-year exposure, the Administrator concludes that use of a 3-year average metric can address the potential for adverse effects to public

welfare that may relate to shorter exposure periods, including a single year.

While the Administrator recognizes the scientific information and interpretations, as well as CASAC advice, with regard to a single-year exposure index, she also takes note of uncertainties associated with judging 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 Administrator is also mindful of the variability in ambient air O<sub>3</sub> concentrations from year to year, as well as year-to-year variability in environmental factors, including rainfall and other meteorological factors, that influence the occurrence and magnitude of O<sub>3</sub>-related effects in any year, and contribute uncertainties to interpretation of the potential for harm to public welfare over the longer term. As noted above, the Administrator also recognizes that the public welfare significance of effects associated with multiple years of critical exposures are potentially greater than those associated with a single year of such exposure. Based on all of these considerations, the Administrator recognizes greater confidence in judgments related to public welfare impacts based on a 3-year average metric. Accordingly, the considerations identified here lead the Administrator to conclude it is appropriate to use an index averaged across three years for judging public welfare protection afforded by a revised secondary standard.

In reaching a conclusion on the amount of public welfare protection from the presence of O<sub>3</sub> in ambient air that is appropriate to be afforded by a revised secondary standard, the Administrator has given particular consideration to the following: (1) The nature and degree of effects of O<sub>3</sub> on vegetation, including her judgments as to what constitutes an adverse effect to the public welfare; (2) the strengths and limitations of the available and relevant information; (3) comments from the public on the Administrator's proposed decision, including comments related to identification of a target level of protection; and (4) CASAC's views regarding the strength of the evidence and its adequacy to inform judgments on public welfare protection. The Administrator recognizes that such judgments include judgments about the interpretation of the evidence and other information, such as the quantitative analyses of air quality monitoring,

exposure and risk. She also recognizes that such judgments should neither overstate nor understate 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 known or anticipated effects judged adverse to the public welfare (as described in section IV.A.3 above). The Administrator additionally recognizes that the choice of the appropriate level of protection is a public welfare policy judgment entrusted to the Administrator under the CAA taking into account both the available evidence and the uncertainties.

The Administrator finds the coherence and strength of the weight of evidence concerning effects on vegetation from the large body of available literature compelling. The currently available evidence addresses a broad array of O<sub>3</sub>-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. She is also mindful of the significance of community composition changes, particularly in protected areas, such as Class I areas. At the same time, she recognizes, while the evidence strongly supports conclusions regarding O<sub>3</sub> impacts on growth and the evidence showing effects on tree seedlings, as well as on older trees, there are limitations in our ability to predict impacts in the environment or to estimate air quality or exposures that will avoid such impacts. Such limitations relate to the variability of environmental factors or characteristics that can influence the extent of O<sub>3</sub> effects.

In recognition of the CASAC advice and the potential for adverse public welfare effects, the Administrator has considered the nature and degree of effects of O<sub>3</sub> on the public welfare. In so doing, the Administrator recognizes that the significance to the public welfare of O<sub>3</sub>-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<sub>3</sub>-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, a residential or commercial setting, or elsewhere. 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<sub>3</sub>-related vegetation effects should be taken into consideration in making judgments with regard to the level of ambient O<sub>3</sub> 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<sub>3</sub>-related vegetation and ecosystem effects identified and discussed in this notice, particular significance should be ascribed to those that may occur on sensitive species that are known to or are likely to occur in 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, for residents on those lands, as well as visitors to those areas.

Likewise, the Administrator also notes that less protection related to growth effects may be called for in the case of other types of vegetation or vegetation associated with other uses or services. For example, the maintenance of adequate agricultural crop yields is extremely important to the public welfare and currently involves the application of intensive management practices. With respect to commercial production of commodities, the Administrator notes that judgments about the extent to which O<sub>3</sub>-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<sub>3</sub>-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 commercial commodities, such as timber, may affect producers and consumers differently, further complicating the question of assessing overall public welfare impacts. Thus, the Administrator

concludes, while research on agricultural crop species remains useful in illuminating mechanisms of action and physiological processes, information from this sector on O<sub>3</sub>-induced effects is considered less useful in informing judgments on what specific standard would provide the appropriate public welfare protection. In so doing, the Administrator notes that a standard revised to increase protection for forested ecosystems would also be expected to provide some increased protection for agricultural crops and other commercial commodities, such as timber.

The Administrator also recognizes that O<sub>3</sub>-related effects on sensitive vegetation can occur in other areas that have not been afforded special federal or other protections, including 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 involving 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 considerations, in identifying the appropriate level of protection for the secondary standard, the Administrator finds it appropriate to focus on sensitive trees and other native species known or anticipated to occur in protected areas such as Class I areas or on other lands set aside by the Congress, 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. In light of their public welfare significance, the Administrator gives particular weight to protecting such vegetation and ecosystems. Given the reasons for the special protection afforded such areas (identified in section I.A.3 above), she recognizes the importance of protecting these natural forests from O<sub>3</sub>-induced impacts, including those related to O<sub>3</sub> effects on growth, and including those extending in scale from individual plants to the ecosystem. The Administrator also recognizes that the impacts identified for O<sub>3</sub> range from those for which the public welfare significance may be more easily judged, but for which quantitative relationships

with O<sub>3</sub> in ambient air are less well established, such as impacts on forest community composition in protected wilderness areas, carbon storage and other important ecosystem services, to specific plant-level effects, such as growth impacts (in terms of RBL) in tree seedlings, for which our quantitative estimates are more robust.

For considering the appropriate public welfare protection objective for a revised standard, the Administrator finds appropriate and useful the estimates of tree seedling growth impacts (in terms of RBL) associated with a range of W126-based index values developed from the robust E-R functions for 11 tree species, that were described in the PA and proposal and are summarized in Table 4 above. In making judgments based on those observations, however, the Administrator has considered the broader evidence base and public welfare implications, including associated strengths, limitations and uncertainties. Thus, in drawing on estimates from this table, she is not making judgments simply about a specific magnitude of growth effect in seedlings that would be acceptable or unacceptable in the natural environment. Rather, the Administrator is using the estimates in the table, as suggested by CASAC and emphasized by some commenters, as a surrogate or proxy for consideration of the broader array of vegetation-related effects of potential public welfare significance, that include effects on growth of individual sensitive species and extend to ecosystem-level effects, such as community composition in natural forests, particularly in protected public lands, as well as forest productivity. In so doing, she notes that CASAC similarly viewed biomass loss as “a scientifically valid surrogate of a variety of adverse effects to public welfare” (Frey, 2014c, p. 10). Thus, in considering the appropriate level of public welfare protection for the revised standard, the Administrator gives primary attention to the relationship between W126 exposures and estimates of RBL in tree seedlings in Table 4, finding this to be a useful quantitative tool to inform her judgments in this matter.

In considering the RBL estimates in Table 4 above (drawn from the final PA), the Administrator takes note of comments from CASAC that also give weight to these relationships in formulating its advice and notes the CASAC comments on specific RBL values (Frey, 2014c). In so doing, she considers and contrasts comments and

their context on RBL estimates of 2% and 6% for the median studied species.

With regard to the CASAC advice regarding 2% RBL for the median studied tree species, the Administrator notes, as an initial matter, the unclear basis for such a focus, as described in section IV.C.2 above and in the proposal. Further, she notes that the CASAC advice related to this RBL value was that it would be appropriate for the range of levels identified in the PA for the Administrator’s consideration to “include[] levels that aim for not greater than 2% RBL for the median tree species” (Frey, 2014c, p. 14). As described in the proposal, the range identified in the PA, which the Administrator considered, extended down to W126 index levels for which the estimated RBL in the median tree species is less than or equal to 2%, consistent with the CASAC advice. In addition, the Administrator notes that only the lowest portion of this range (7–8 ppm-hrs) corresponds to an estimated RBL for the median tree species of less than or equal to 2%, with the remainder of CASAC’s range (up to 15 ppm-hrs) associated with higher median RBL estimates. Thus, the Administrator understands CASAC to have identified 2% RBL for the median tree species as a benchmark falling within, and at one end of, the range of levels of protection that the CASAC considers appropriate for the revised standard to provide. However, the fact that the CASAC range included levels for which the RBL estimates were appreciably greater than 2% indicates that CASAC did not judge it necessary that the revised standard be based on the 2% RBL benchmark. Accordingly, the Administrator proposed revisions to the secondary standard based on options related to higher RBL estimates and associated exposures. After also considering public comments, the Administrator continues to consider the uncertainty regarding the extent to which associated effects on vegetation at lower O<sub>3</sub> exposures would be adverse to public welfare to be too great to provide a foundation for public welfare protection objectives for a revised secondary standard.

With regard to the CASAC comments on a 6% RBL estimate, the Administrator takes particular note of their characterization of this level of effect in the median studied species as “unacceptably high” (Frey, 2014c, pp. iii, 13, 14). These comments were provided in the context of CASAC’s considering the significance of effects associated with a range of alternatives for the secondary standard. Moreover, the range recommended by CASAC excluded W126 index values for which

the median species was estimated to have a 6% RBL,<sup>212</sup> based on the information before CASAC at the time (Frey, 2014c, p. 12–13). Accordingly, the EPA interprets these comments regarding 6% RBL to be of a different nature than the CASAC advice regarding a 2% median RBL, both because these two comments are framed to address different questions and because CASAC treated them differently in its recommended range.

In the Administrator’s consideration of the RBL estimates to inform judgments on O<sub>3</sub> exposures of concern to public welfare and the appropriate protection that the secondary standard should provide from such exposures, she has given particular consideration to the current evidence for the relationship of reduced growth of sensitive tree species with ecosystem effects (as described in the ISA), CASAC’s view of 6% RBL for the median studied species as unacceptably high, and the role of the Administrator’s judgments regarding public welfare impacts of effects in specially protected natural systems, such as Class I areas. With regard to a point of focus among the median RBL estimates extending below 6% for purposes of judging the appropriate public welfare protection objectives for a revised secondary standard, the Administrator is mindful of the CASAC advice to consider lower levels if using a 3-year average, rather than annual, W126 index value.

In considering the CASAC advice, the Administrator notes that her judgments on a 3-year average index focus on the level of confidence in conclusions that might be drawn with regard to single as compared to multiple year impacts, as described above. For example, the Administrator, while recognizing the strength of the evidence with regard to quantitative characterization of O<sub>3</sub> effects on growth of tree seedlings and crops, and in addition to noting the additional difficulties for assessing the welfare impacts of O<sub>3</sub> on crops, takes note of the uncertainty associated with

<sup>212</sup> As summarized in IV.C.2 above (and noted in section IV.E.3 of the proposal), revisions to this table in the final PA, made in consideration of other 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%), the review of which was the context for CASAC’s advice on this point (Frey, 2014c). The median RBL estimate ranges from 5.3% to 3.8% across the range of W126 exposures (17 ppm-hrs to 13 ppm-hrs) that the Administrator proposed to conclude would provide the appropriate public welfare protection for a revised secondary standard.

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<sub>3</sub>. Moreover, as explained above, the Administrator concludes that concerns related to the possibility of a single unusually damaging year, inclusive of those described by the CASAC, can be addressed through use of a 3-year average metric. Thus, similar to the CASAC's view that a lower level would be appropriate with a 3-year form, the Administrator considers it appropriate to focus on a standard that would generally limit cumulative exposures to those for which the median RBL estimate would be somewhat lower than 6%.

In focusing on cumulative exposures associated with a median RBL estimate somewhat below 6%, the Administrator considers the relationships in Table 4, noting that the median RBL estimate is 6% for a cumulative seasonal W126 exposure index of 19 ppm-hrs. Considering somewhat lower values, the median RBL estimate is 5.7% (which rounds to 6%) for a cumulative seasonal W126 exposure index of 18 ppm-hrs and the median RBL estimate is 5.3% (which rounds to 5%) for 17 ppm-hrs. In light of her decision that it is appropriate to use a 3-year cumulative exposure index for assessing vegetation effects (described above), the potential for single-season effects of concern, and CASAC comments on the appropriateness of a lower value for a 3-year average W126 index, the Administrator concludes it is appropriate to identify a standard that would restrict cumulative seasonal exposures to 17 ppm-hrs or lower, in terms of a 3-year W126 index, in nearly all instances. In reaching this conclusion, based on the current information to inform consideration of vegetation effects and their potential adversity to public welfare, she additionally judges that the RBL estimates associated with marginally higher exposures in isolated, rare instances are not indicative of effects that would be adverse to the public welfare, particularly in light of variability in the array of environmental factors that can influence O<sub>3</sub> effects in different systems and uncertainties associated with estimates of effects associated with this magnitude of cumulative exposure in the natural environment.

While giving primary consideration to growth effects using the surrogate of RBL estimates based on tree seedling effects, the Administrator also

recognizes the longstanding and robust evidence of O<sub>3</sub> effects on crop yield. She takes note of CASAC concurrence with the PA description of such effects as of public welfare significance and agrees. As recognized in the proposal, the maintenance of adequate agricultural crop yields is extremely important to the public welfare. Accordingly, research on agricultural crop species remains important for further illumination of mechanisms of action and physiological processes. Given that the extensive management of such vegetation, which as CASAC noted may reduce yield variability, may also to some degree mitigate potential O<sub>3</sub>-related effects, however, judgments about the extent to which O<sub>3</sub>-related effects on crop yields are adverse from a public welfare perspective are particularly difficult to reach. Further, management practices for agricultural crops are highly variable and generally designed to achieve optimal yields, taking into consideration various environmental conditions. As a result of this extensive role of management in optimizing crop yield, the Administrator notes the potential for greater uncertainty with regard to estimating the impacts of O<sub>3</sub> exposure on agricultural crop production than that associated with O<sub>3</sub> impacts on vegetation in natural forests. For all of these reasons, the Administrator is not giving the same weight to CASAC's statement regarding crop yield loss as a surrogate for adverse effects on public welfare, or the magnitude that would represent an adverse impact to public welfare, as to the CASAC's comments on RBL as a surrogate for an array of growth-related effects. Similarly, given the considerations summarized above and in the proposal, the Administrator concludes that agricultural crops do not have the same need for additional protection from the NAAQS as forested ecosystems and finds protection of public welfare from crop yield impacts to be a less important consideration in this review for the reasons identified, including the extensive management of crop yields and the dynamics of agricultural markets. Thus, the Administrator is not giving a primary focus to crop yield loss in selecting a revised secondary standard. She notes, however, that a standard revised to increase protection for forested ecosystems would also be expected to provide some increased protection for agricultural crops.

The Administrator has additionally considered the evidence and analyses of visible foliar injury. In so doing, the Administrator notes the ISA conclusion

that "[e]xperimental evidence has clearly established a consistent association of visible injury with O<sub>3</sub> exposure, with greater exposure often resulting in greater and more prevalent injury" (U.S. EPA, 2013, section 9.4.2, p. 9–41). The Administrator also recognizes the potential for this effect to affect the public welfare in the context of affecting values pertaining to natural forests, particularly those afforded special government protection, as discussed in section IV.A.3 above. However, she recognizes significant challenges in judging the specific extent and severity at which such effects should be considered adverse to public welfare, in light of the variability in the occurrence of visible foliar injury and the lack of clear quantitative relationships 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.

Further, the Administrator takes note of the range of evidence on visible foliar injury and the various related analyses, including additional observations drawn from the WREA biosite dataset in response to comments, as summarized in section IV.C.2 above. In so doing, she does not agree with CASAC's comment that a level of W126 exposure below 10 ppm-hrs is required to reduce foliar injury, noting some lack of clarity in the WREA and PA presentations of the WREA cumulative proportion analysis findings and their meaning (described in section IV.C.2.b above). She notes that the additional observations summarized in section IV.C.2 above indicate declines in proportions of sites with any visible foliar injury and biosite index scores with reductions in cumulative W126 exposure across a range of values extending at the high end well above 20 ppm-hrs, down past and including 17 ppm-hrs. In considering this information, however, the Administrator takes note of the current lack of robust exposure-response functions that would allow prediction of visible foliar injury severity and incidence under varying air quality and environmental conditions, as recognized in section IV.A.1.b above. Thus, while the Administrator notes that the evidence is not conducive to use for identification of a specific quantitative public welfare protection objective, due to uncertainties and complexities described in sections IV.A.1.b and IV.A.3 above, she concludes that her judgments above, reached with a focus on RBL estimates, would also be expected to provide an additional

desirable degree of protection against visible foliar injury in sensitive vegetation. Accordingly, she considers a conclusion on the appropriateness of selecting a standard that will generally limit cumulative exposures above 17 ppm-hrs to be additionally supported by evidence for visible foliar injury, while not based on specific consideration of this effect.

With the public welfare protection objectives identified above in mind, the Administrator turns to her consideration of form and level for the revised secondary standard. In considering whether the current form should be retained or revised in order to provide the appropriate degree of public welfare protection, the Administrator has considered the analyses of air quality data from the last 13 years that describe the cumulative exposures, in terms of a 3-year W126 index, occurring at monitoring sites across the U.S. when the air quality metric at that location, in terms of the current standard's form and averaging time, is at or below different alternative levels. The Administrator notes both the conclusions drawn from analyses of the strong, positive relationship between these metrics and the findings that indicate the amount of control provided by the fourth-high metric.

The Administrator has also considered advice from CASAC and public commenters that support revision of the form to the W126 exposure index. The Administrator concurs with the underlying premise that O<sub>3</sub> effects on vegetation are most directly assessed using a cumulative seasonal exposure index, specifically the W126 exposure index. The Administrator additionally recognizes, based on analyses of the last 13 years of monitoring data, and consideration of modeling analyses with associated limitations and uncertainties, that cumulative seasonal exposures appear to have a strong relationship with design values based on the current form and averaging time. She additionally notes the correlation of reductions in W126 index values with reductions in precursor emissions over the past decade that were targeted at meeting the current O<sub>3</sub> standards (with fourth-high form), which indicate the control of cumulative seasonal exposures that can be achieved with a standard of the current form and averaging time.

With regard to recommendations from the CASAC that the form for the revised secondary standard should be the biologically relevant exposure metric, and related comments from the public indicating that the secondary standard must have such a form, the

Administrator disagrees. In so doing, she notes that CAA section 109 does not impose such a requirement on the form or averaging time for the NAAQS, as explained in IV.C.2 above. She further notes that the averaging time and form of primary standards are often not the same as the exposure metrics used in reviews of primary standards, in which specific information on quantitative relationships between different exposure metrics and health risk is more often available than it is in reviews of secondary NAAQS. As discussed in section IV.C.2 above, with examples, a primary standard with a particular averaging time and form may provide the requisite public health protection from health effects that are most appropriately assessed using an exposure metric of a different averaging time and form and indicator, and the same principle can apply when establishing or revising secondary standards. The Administrator recognizes that the exposure metric and the standard metric can be quite similar, as in the case of consideration of short-term health effects with the primary O<sub>3</sub> standard. She also notes, however, as illustrated by the examples described in section IV.C.2 above, that it is not uncommon for the EPA to retain or adopt elements of an existing standard that the Administrator judges in combination across all elements, including in some cases a revised level, to provide the requisite protection under the Act, even if those elements do not neatly correspond to the exposure metric. Accordingly, she concludes that the Act does not require that the secondary O<sub>3</sub> standard be revised to match the exposure metric identified as biologically relevant in this review, as long as the revised standard provides the degree of protection required under CAA section 109(b)(2).

Based on the considerations described here, including the use of an exposure metric that CASAC has agreed to be biologically relevant and appropriate, related considerations summarized in the proposal with regard to air quality analyses and common uses of exposure metrics in other NAAQS reviews, the Administrator finds that, in combination with a revised level, the current form and averaging time for a revised secondary standard can be expected to provide the desired level of public welfare protection. Accordingly, she next turns to the important consideration of a level that, in combination with the form and averaging time, will yield a standard that specifies the requisite air quality for protection of public welfare. In so

doing, she has recognized the recommendation by CASAC for revision of the form and averaging time and provided the basis for her alternative view, as described above. Further, in the context of the Administrator's decision on objectives for public welfare protection of a revised secondary standard, and with consideration of the advice from CASAC on levels for a W126-based standard, the Administrator has also reached the conclusion, as described above, that in order to provide the appropriate degree of public welfare protection, the revised secondary standard should restrict cumulative seasonal exposures to 17 ppm-hrs or lower, in terms of a 3-year average W126 index, in nearly all instances. Thus, the Administrator finds it appropriate to revise the standard level to one that, in combination with the form and averaging time, will exert this desired degree of control for cumulative seasonal exposures.

In considering a revised standard level, the Administrator has, in light of public comments, revisited the information she considered in reaching her proposed decision on a level within the range of 65 to 70 ppb, and additional information or insights conveyed with public comments. The primary focus of the Administrator's considerations in reaching her proposed decision was the multi-faceted analysis of air quality data from 2001 through 2013 documented in the technical memo in the docket (Wells, 2014a), as well as the earlier analyses and related information described in the PA (as summarized in section IV.E.4 of the proposal). This analysis describes the occurrences of 3-year W126 index values of a magnitude from 17 ppm-hrs through 7 ppm-hrs at monitor locations where O<sub>3</sub> concentrations met different alternative standards with the current form and averaging time, and has been expanded in consideration of public comments to present in summary form the more extensive historical dataset accompanying this analysis (Wells, 2015b). Focusing first on the air quality analyses for the most recent period for which data are available (2011–2013) and with the protection objectives identified above in mind, the Administrator observes that across the sites meeting the current standard of 75 ppb, the analysis finds 25 sites distributed across different NOAA climatic regions with 3-year average W126 index values above 17 ppm-hrs, with the values at nearly half of the sites extending above 19 ppm-hrs, with some well above. In comparison, she observes that across sites meeting an alternative

standard of 70 ppb, the analysis for the period from 2011–2013 finds no occurrences of W126 metric values above 17 ppm-hrs and less than a handful of occurrences that equal 17 ppm-hrs. The more than 500 monitors that would meet an alternative standard of 70 ppb during the 2011–2013 period are distributed across all nine NOAA climatic regions and 46 of the 50 states (Wells, 2015b and associated dataset in the docket).

The Administrator notes that some public commenters, who disagreed with her proposed decision on form and averaging time, emphasized past occurrences of cumulative W126 exposure values above the range identified in the proposal (of 13 to 17 ppm-hrs). For example, these commenters emphasize data from farther back across the full time period of the dataset analyzed in the technical memorandum (2001–2013), identifying a value of 19.1 ppm-hrs at a monitor for which the fourth-high metric is 70 ppb for the 3-year period of 2006–2008. The Administrator notes, as discussed in section IV.C.2 above, that this was one of fewer than a handful of isolated occurrences of sites for which the fourth-high was at or below 70 ppb and the W126 index value was above 17 ppm-hrs, all but one of which were below 19 ppm-hrs. The Administrator additionally recognizes her underlying objective of a revised secondary standard that would limit cumulative exposures in nearly all instances to those for which the median RBL estimate would be somewhat lower than 6%. She observes that the single occurrence of 19 ppm-hrs identified by the commenter among the nearly 4000 3-year W126 index values from across the most recently available 11 3-year periods of data at monitors for which the fourth-high metric is at or below 70 ppb is reasonably regarded as an extremely rare and isolated occurrence (Wells, 2015b). As such, it is unclear whether it would recur, particularly as areas take further steps to reduce O<sub>3</sub> to meet revised primary and secondary standards. Further, based on the currently available information, the Administrator does not judge RBL estimates associated with marginally higher exposures in isolated, rare instances to be indicative of adverse effects to the public welfare. Thus, the Administrator concludes that a standard with a level of 70 ppb and the current form and averaging time may be expected to limit cumulative exposures, in terms of a 3-year average W126 exposure index, to values at or below 17 ppm-hrs, in nearly all instances, and

accordingly, to eliminate or virtually eliminate cumulative exposures associated with a median RBL of 6% or greater.

The Administrator recognizes that any standard intended to exert a very high degree of control on cumulative seasonal exposures, with the objective of limiting exposures above 17 ppm-hrs across the U.S., in nearly all instances, will, due to regional variation in meteorology and sources of O<sub>3</sub> precursors, result in cumulative seasonal exposures well below 17 ppm-hrs in many areas. Even implementation of a standard set in terms of the cumulative seasonal exposure metric, while limiting the highest exposures, would, due to regional variation in meteorology and sources of O<sub>3</sub> precursors, result in many areas with much lower exposures. Such variation in exposures occurring under a specific standard is not unexpected and the overall distribution of exposures estimated to occur with air quality conditions associated with different alternative standards is a routine part of the consideration of public health protection in reviews of primary standards, and can also play a role in the review of secondary standards. For these reasons, and in light of the discussion in section IV.C.2.d above on consideration of “necessary” protection, the Administrator notes that an expectation of differing exposures is not, in itself, a basis for concluding that the air quality would be more (or less) than necessary (and thus not requisite) for the desired level of public welfare protection.

The Administrator has also considered the protection afforded by a revised standard against other effects studied in this review, such as visible foliar injury and reduced yield for agricultural crops, and also including those associated with climate change. While noting the evidence supporting a relationship of O<sub>3</sub> in ambient air with climate forcing effects, as concluded in the ISA, the Administrator judges the quantitative uncertainties to be too great to support identification of a standard specific to such effects such that she concludes it is more important to focus, as she has done above, on setting a standard based on providing protection against vegetation-related effects which would be expected to also have positive implications for climate change protection through the protection of ecosystem carbon storage.

The Administrator additionally considers the extent of control for cumulative seasonal exposures exerted by a revised standard level of 65 ppb, the lower end of the proposed range. In

focusing on the air quality analyses for the most recent 3-year period for which data are available, the Administrator observes that across the sites meeting a fourth-high metric of 65 ppb, the analysis finds no occurrences of W126 metric values above 11 ppm-hrs and 35 occurrences of a value between 7 ppm-hrs and 11 ppm-hrs, scattered across NOAA climatic regions. The Administrator finds these magnitudes of cumulative seasonal exposures to extend appreciably below the objectives she identified above for affording public welfare protection. In considering this alternative level, she additionally notes that data for only 276 monitors (less than 25 percent of the total with valid fourth-high and W126 metric values) were at or below a fourth-high value of 65 ppb during the period from 2011–2013. In so noting, she recognizes the appreciably smaller and less geographically extensive dataset available and the associated uncertainty for conclusions based on such an analysis.

Thus, based on the support provided by currently available information on air quality, the evidence base of O<sub>3</sub> effects on vegetation and her public welfare policy judgments, and after carefully taking the above comments and considerations into account, fully considering the scientific views of the CASAC, and also taking note of CASAC’s policy views, the Administrator has decided to retain the current indicator, form and averaging time and to revise the secondary standard level to 70 ppb. In the Administrator’s judgment, based on the currently available evidence and quantitative exposure and air quality information, a standard set at this level, in combination with the currently specified form, averaging time and indicator would be requisite to protect the public welfare from known or anticipated adverse effects. A standard set at this level provides an appreciable increase in protection compared to the current standard. The Administrator judges that such a standard would protect natural forests in Class I and other similarly protected areas against an array of adverse vegetation effects, most notably including those related to effects on growth and productivity in sensitive tree species. The Administrator believes that a standard set at 70 ppb would be sufficient to protect public welfare from known or anticipated adverse effects and believes that a lower standard would be more than what is necessary to provide such protection. This judgment by the Administrator appropriately recognizes

that the CAA does not require that standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects. Accordingly, the Administrator concludes that it is appropriate to revise the level for the secondary standard to 70 ppb (0.070 ppm), in combination with retaining the current form, indicator, and averaging time, in order to specify the level of air quality that provides the requisite protection to the public welfare from any known or anticipated adverse effects associated with the presence of O<sub>3</sub> in the ambient air.

#### D. Decision on the Secondary Standard

For the reasons discussed above, and taking into account information and assessments presented in the ISA and PA, the advice and recommendations of CASAC, and the public comments, as well as public welfare judgments, the Administrator is revising the level of the current secondary standard. Specifically, the Administrator has decided to revise the level of the secondary standard to a level of 0.070 ppm, in conjunction with retaining the current indicator, averaging time and form. Accordingly the revised secondary standard is 0.070 ppm O<sub>3</sub>, as the annual fourth-highest daily maximum 8-hour average concentration, averaged over three years.

### V. Appendix U: Interpretation of the Primary and Secondary NAAQS for O<sub>3</sub>

#### A. Background

The EPA is finalizing the proposed Appendix U to 40 CFR part 50: Interpretation of the Primary and Secondary National Ambient Air Quality Standards for Ozone. The proposed Appendix U addressed the selection of ambient O<sub>3</sub> monitoring data to be used in making comparisons with the NAAQS, data reporting and data handling conventions for comparing ambient O<sub>3</sub> monitoring data with the level of the NAAQS, and data completeness requirements. The EPA solicited public comment on four elements where the proposed Appendix U differed from Appendix P to 40 CFR part 50, which addressed data handling conventions for the previous O<sub>3</sub> NAAQS. These included the following: (1) the addition of a procedure to combine data collected from two or more O<sub>3</sub> monitors operating simultaneously at the same physical location, (2) the addition of a provision allowing the Regional Administrator to approve "site combinations", or the combination of data from two nearby

monitoring sites for the purpose of calculating a valid design value, (3) a change from the use of one-half of the method detection limit (½ MDL) to zero (0.000 ppm) as the substitution value in 8-hour average data substitution tests, and 4) a new procedure for calculating daily maximum 8-hour average O<sub>3</sub> concentrations for the revised NAAQS.

The EPA is also finalizing, as proposed, exceptional events scheduling provisions in 40 CFR 50.14 that will apply to the submission of information supporting claimed exceptional events affecting pollutant data that are intended to be used in the initial area designations for any new or revised NAAQS. The new scheduling provisions will apply to initial area designations for the 2015 O<sub>3</sub> NAAQS.

#### B. Data Selection Requirements

The EPA proposed this section in Appendix U to clarify which data are to be used in comparisons with the revised O<sub>3</sub> NAAQS. The EPA is finalizing this section in Appendix U as proposed.

First, the EPA proposed to combine data at monitoring sites with two or more O<sub>3</sub> monitoring instruments operating simultaneously into a single site-level data record for determining compliance with the NAAQS, and proposed an analytical approach to perform this combination (79 FR 75351–75352, December 17, 2014). Several commenters supported the EPA's proposed approach, including the State of Iowa, where 15 of the 20 monitoring sites currently operating two O<sub>3</sub> monitors simultaneously are located. Commenters supporting the proposal noted that a similar approach is already being used for lead and particulate monitoring, and that the proposed approach will help states meet data completeness requirements.

A few commenters supported the EPA's proposed approach with the additional restrictions that the monitoring instruments must use identical methods and be operated by the same monitoring agency. The EPA notes that at the time of this rulemaking, all monitors reporting O<sub>3</sub> concentration data to the EPA for regulatory use were FEMs. All current O<sub>3</sub> FEMs use an ultraviolet photometry sampling methodology and have been found to meet the performance criteria in 40 CFR part 53. Therefore, the EPA has no reason to believe that O<sub>3</sub> concentration data should not be combined across monitoring methods at the site level. Regarding the commenters' suggestion that data should not be combined when two or more monitors at the same site are operated by different monitoring agencies, the EPA is aware of only one

instance where this presently occurs. In this instance, the monitors have been assigned distinct site ID numbers in the AQS database, so that data will not be combined across these monitors. Should future instances arise where two or more monitoring agencies decide to operate O<sub>3</sub> monitors at the same site, the EPA encourages these agencies to work together to establish a plan for how the data collected from these monitors should be used in regulatory decision making.

One state objected to combining data across monitors because the secondary monitors at their sites were used only for quality assurance purposes and data from these monitors should not be combined with data reported from the primary monitors. The EPA notes that concentration data collected to meet quality assurance requirements (*i.e.* precision and bias data) are reported and stored in a separate location within the AQS database and are not used for determining compliance with the NAAQS. The required quality assurance data are derived from O<sub>3</sub> standards and not from a separate O<sub>3</sub> monitor. However, if a separate O<sub>3</sub> monitor is used strictly for quality assurance purposes and does not meet the applicable monitoring requirements, it can be distinguished in AQS in such a manner that data from the secondary monitor would not be combined with data from the primary monitor.

Another commenter objected to the proposal because it would reduce the total number of comparisons made with the NAAQS. While this is true, the number of physical locations being compared with the NAAQS will not decrease under the proposed approach, and in fact may increase due to additional sites meeting the data completeness requirements.

Finally, two commenters submitted similar comments citing the EPA's evaluation of collocated O<sub>3</sub> monitoring data and precision data in the ISA (U.S. EPA, 2013, section 3.5.2), and stated that although the median differences in concentrations reported by the pairs of monitoring instruments were near zero, the extreme values were close to +/– 3.5%. The commenter argued that since the O<sub>3</sub> NAAQS are based on the fourth-highest annual value, data should not be combined across monitors because of the imprecision in the extreme values. The EPA disagrees, noting that the data presented in the ISA are based on hourly concentrations, while design values for the O<sub>3</sub> NAAQS are based on a 3-year average of 8-hour average concentrations. Thus, the random variability in the hourly O<sub>3</sub> concentration data due to monitoring



imprecision will be reduced when concentrations are averaged for comparison with the NAAQS. Additionally, the precision data are typically collected at concentrations at or above the level of the NAAQS, thus the EPA expects that the level of precision documented in the ISA analysis is consistent with the level of precision in the fourth-highest daily maximum concentrations used for determining compliance with the NAAQS.

The EPA is finalizing this addition in Appendix U as proposed. In addition, the AQS database will be updated to require state agencies to designate a primary monitor at O<sub>3</sub> monitoring sites that report data under more than one Pollutant Occurrence Code (POC), a numeric indicator in AQS used to identify individual monitoring instruments. O<sub>3</sub> design value calculations in AQS will be updated so that the data will automatically be combined across POCs at a site, and a single design value will be reported for each site. The EPA notes that the substitution approach described above will only be applied to design value calculations for the revised O<sub>3</sub> standards, and that design values for previous O<sub>3</sub> standards will continue to be calculated at the monitor level, in accordance with the applicable appendices of 40 CFR part 50.

Second, the EPA proposed to add a provision in Appendix U that would allow the Regional Administrator to approve "site combinations", or to combine data across two nearby monitors for the purpose of calculating a valid design value. Although data handling appendices for previous O<sub>3</sub> standards do not explicitly mention site combinations, the EPA has approved over 100 site combinations since the promulgation of the first 8-hour O<sub>3</sub> NAAQS in 1997. Thus, the EPA's intention in proposing this addition was merely to codify an existing convention, and to improve transparency by implementing site combinations in AQS design value calculations.

Public commenters unanimously supported this proposed addition. Two commenters suggested that the EPA should require monitoring agencies to provide technical documentation supporting the similarities between sites approved for combining data, including a requirement for simultaneous monitoring whenever possible. One state requested that the EPA provide more detailed acceptability criteria for approving site combinations, while another state urged the EPA not to create a regulatory burden by

prescribing detailed requirements codified in regulations.

The EPA is finalizing this addition as proposed in Appendix U. The EPA believes that approval of site combinations should be handled on a case-by-case basis, and that any requests for supporting documentation should be left to the discretion of the Regional Administrator. The EPA may issue future guidance providing general criteria for determining an acceptable level of similarity in air quality concentrations between monitored locations, but is not prescribing detailed criteria for approval of site combinations in this rulemaking.

Additionally, the AQS database will be updated with new fields for monitoring agencies to request site combinations, and an additional field indicating Regional Administrator approval. All pre-existing site combinations will be initially entered into the database as having already been approved by the Regional Administrator. Since this provision has already been used in practice under previous O<sub>3</sub> standards, site combinations will be applied to AQS design value calculations for both the revised O<sub>3</sub> standards and previous O<sub>3</sub> standards.

### *C. Data Reporting and Data Handling Requirements*

First, the EPA proposed a change in Appendix U to the pre-existing 8-hour average data substitution test (40 CFR part 50, Appendix P, section 2.1) which is used to determine if a site would have had a valid 8-hour average greater than the NAAQS when fewer than 6 hourly O<sub>3</sub> concentration values are available for a given 8-hour period. The EPA proposed to change the value substituted for the missing hourly concentrations from one-half of the method detection limit of the O<sub>3</sub> monitoring instrument (1/2 MDL) to zero (0.000 ppm).

Several commenters supported the proposed change, stating that the use of a constant substitution value instead of 1/2 MDL, which can vary across O<sub>3</sub> monitoring methods, would simplify design value calculations. One commenter noted that with a substitution value of zero, the data substitution test for an 8-hour average value greater than the NAAQS is equivalent to a sum of hourly O<sub>3</sub> concentrations greater than 0.567 ppm (*i.e.*, if the sum is 0.568 ppm or higher, the resulting 8-hour average must be at least 0.071 ppm, which is greater than the revised O<sub>3</sub> NAAQS of 0.070 ppm). Finally, one commenter opposed the proposed change in favor of some type

of mathematical or statistical interpolation approach, but did not provide a specific recommendation.

The EPA is finalizing the proposed change in Appendix U, with the addition of a short clause making note of the equivalent summation approach described above. The purpose of the data substitution test is to identify 8-hour periods that do not meet the requirements for a valid 8-hour average, yet the reported hourly concentration values are so high that the NAAQS would have been exceeded regardless of the magnitude of the missing concentration values. The EPA believes that zero, being the lowest measured O<sub>3</sub> concentration physically possible, is the most appropriate value to substitute in this situation. Additionally, the EPA does not support the use of interpolation or other means of filling in missing monitoring data for O<sub>3</sub> NAAQS comparisons. Such an approach would be contrary to the EPA's long-standing policy of using only quality-assured and certified ambient air quality measurement data to determine compliance with the O<sub>3</sub> NAAQS.

Second, the EPA proposed a new procedure in Appendix U for determining daily maximum 8-hour O<sub>3</sub> concentrations for the revised NAAQS.<sup>213</sup> The EPA proposed to determine the daily maximum 8-hour O<sub>3</sub> concentration based on 17 consecutive moving 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. In addition, the EPA proposed that a daily maximum value would be considered valid if 8-hour averages were available for at least 13 of the 17 consecutive moving 8-hour periods, or if the daily maximum value was greater than the level of the NAAQS. This procedure is designed to eliminate "double counting" exceedances of the NAAQS based on overlapping 8-hour periods from two consecutive days with up to 7 hours in common, which was allowed under previous 8-hour O<sub>3</sub> NAAQS. A dozen public commenters expressed support for the proposed procedure, including several states.

One regional air quality management organization and three of its member states submitted similar comments stating that they agreed with the principle of eliminating "double counting" exceedances of the NAAQS

<sup>213</sup> This procedure will be adopted only for the revised O<sub>3</sub> NAAQS. Design values for the 1997 8-hour O<sub>3</sub> NAAQS and the 2008 8-hour O<sub>3</sub> NAAQS will continue to be calculated according to Appendix I and Appendix P of 40 CFR part 50, respectively.

based on overlapping 8-hour periods, but suggested an alternative calculation procedure that would accomplish the same objective. The alternative procedure iteratively finds the highest 8-hour period in a given year, then removes this 8-hour period and all other 8-hour periods associated with that day, including any overlapping 8-hour periods on adjacent days, from the data until a daily maximum value is determined for each day of the year with sufficient monitoring data. The EPA examined a similar iterative procedure in a previous data analysis supporting the proposal (Wells, 2014b, Method 1). The EPA compared this procedure to the procedure proposed by the commenters using the data from the original analysis and found the resulting daily maximum 8-hour values to be nearly identical (Wells, 2015a). Additionally, the commenters' procedure suffers from the same limitations the EPA identified previously in the original analysis: added complexity in design value calculations, longer computational time, and challenges to real-time O<sub>3</sub> data reporting systems, which would have to re-calculate daily maximum 8-hour values for the entire year each time the system was updated with new data.

Three states submitted comments stating that they agreed with the proposed calculation procedure, but disagreed with the proposed requirements for determining a valid daily maximum 8-hour O<sub>3</sub> concentration. These states were primarily concerned that the proposed requirements would only allow a monitoring site to have four missing 8-hour averages during a day before the entire day would be invalidated, compared with six missing 8-hour averages allowed previously. Two of these states also stated concerns that the proposed requirements would be more difficult to meet while maintaining compliance with existing monitoring requirements such as biweekly quality assurance checks. The EPA compared annual data completeness rates calculated using the Appendix U requirements to annual data completeness rates calculated using the requirements under the previous O<sub>3</sub> standards across all U.S. monitoring sites based on data from 2004–2013 (Wells, 2015a). The national mean annual data completeness rate was 0.1% higher under the proposed Appendix U requirements than under the previous O<sub>3</sub> standards, and the national median annual data completeness rates were identical. In addition, the EPA notes that the Appendix U requirements allow

for biweekly quality assurance checks and other routine maintenance to be performed between 5:00 a.m. and 9:00 a.m. local time without affecting data completeness. Thus, the EPA does not believe that the proposed daily data completeness requirements in Appendix U will be more difficult for monitoring agencies to meet.

Finally, two public commenters opposed the proposed procedures for determining daily maximum 8-hour concentrations. These commenters expressed similar concerns, primarily that not considering 8-hour periods starting midnight to 6:00 a.m. is less protective of public health than the procedure used to determine daily maximum 8-hour concentrations for the previous O<sub>3</sub> standards. The EPA believes that this approach provides the appropriate degree of protection for public health, noting that the hourly concentrations from midnight to 7:00 a.m. are covered under the 8-hour period from 11:00 p.m. to 7:00 a.m., which is included in the design value calculations proposed in Appendix U. At the same time, the proposed approach ensures that individual hourly concentrations may not contribute to multiple exceedances of the NAAQS, which the EPA believes is inappropriate given that people are only exposed once.

The EPA is finalizing as proposed in Appendix U the procedure for determining daily maximum 8-hour concentrations. The EPA does not believe that daily maximum 8-hour concentrations for two consecutive days should be based on overlapping 8-hour periods, since the exposures experienced by individuals only occur once. The EPA believes that the new procedure will avoid this outcome while continuing to make use of all hourly concentrations in determining attainment of the standards, without introducing unnecessary complexity into design value calculations, and without creating additional difficulties for monitoring agencies to meet the data completeness requirements.

#### *D. Exceptional Events Information Submission Schedule*

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 50.14, contains generic deadlines for an air agency to submit to the EPA specified information about exceptional events and associated air pollutant concentration data. As discussed in this section and in more detail in the O<sub>3</sub> NAAQS proposal, without revisions to 40 CFR 50.14, an

air agency may not be able to flag and submit documentation for some relevant data either because the generic deadlines may have already passed by the time a new or revised NAAQS is promulgated or because the generic deadlines require submission of documentation at least 12 months prior to the date by which the EPA must make a regulatory decision, which may be before air agencies have collected some of the potentially affected data. Specific to the revised O<sub>3</sub> NAAQS, revisions to 40 CFR 50.14 are needed because it is not possible for air agencies to flag and submit documentation for any exceptional events that occur in October through December of 2016 by 1 year before the designations are made in October 2017, as is required by the existing generic schedule.

The EPA is finalizing exceptional events scheduling provisions in 40 CFR 50.14, as proposed and as supported by multiple commenters, that will apply to the submission of information supporting claimed exceptional events affecting pollutant data that are intended to be used in the initial area designations for any new or revised NAAQS. The new scheduling provisions will apply to initial area designations for the revised O<sub>3</sub> NAAQS. The provisions that we are promulgating use a “delta schedule” that calculates the timelines associated with flagging data potentially influenced by exceptional events, submitting initial event descriptions and submitting exceptional events demonstrations based on the promulgation date of a new or revised NAAQS. 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) continue to apply to data used in regulatory decisions other than those related to the initial area designations process under a new or revised NAAQS.<sup>214</sup>

The EPA acknowledges the concern raised by several commenters that a strengthened O<sub>3</sub> NAAQS may result in numerous demonstrations for exceptional events occurring between 2014 and 2016, the data years that the EPA will presumably use for initial area designation decisions made in October 2017.<sup>215</sup> Commenters noted that the proposed schedule is particularly burdensome for agencies needing to submit exceptional events packages for

<sup>214</sup> The EPA intends to consider changes to these retained scheduling requirements as part of the planned notice and comment rulemaking revisions to the 2007 Exceptional Events Rule.

<sup>215</sup> Governors may also use 2013 data to formulate their recommendations regarding designations.

the third year to be used in a 3-year design value (*i.e.*, 2016 data). Several commenters recommended that the EPA either establish no defined schedule for data flagging and exceptional events demonstration submittal or allow a minimum of 2 years from the setting of any new or revised NAAQS for air agencies to provide a complete exceptional events demonstration. Given the CAA requirement that the EPA follow a 2-year designations schedule, the EPA cannot remove submittal schedules entirely for data influenced by exceptional events or provide a minimum 2-year period from the setting of a new or revised NAAQS for documentation submittal. Neither of these options would ensure that the EPA has time to consider event-influenced data in initial area designation decisions. Rather, the EPA is promulgating in this action an exceptional events schedule that provides air agencies with the maximum amount of time available to prepare exceptional events demonstrations and will still allow the EPA sufficient time to consider such exceptional events demonstrations in the designations process in advance of the date by which the EPA must send 120-day notification letters to states.<sup>216</sup> The EPA recognizes that the schedule promulgated in this action is compressed, particularly for the third year of data to be used in a 3-year design value, and we will work cooperatively with air agencies to accommodate this scenario.

Under the schedule promulgated in this action and assuming initial area designation decisions in October 2017 for the revised O<sub>3</sub> NAAQS, affected air agencies would need to flag data, submit initial event descriptions and submit demonstrations for exceptional events occurring in 2016 by May 31, 2017. This schedule provides approximately 5 months between the EPA's receipt of the demonstration package and the expected date of designation decisions and approximately 1 month between the EPA's receipt of a package and the date by which the EPA must notify states and tribes of intended modifications to the Governors' recommendations for designations (*i.e.*, 120-day letters).

While, for the third year of data anticipated to be used in a 3-year design value for the revised O<sub>3</sub> NAAQS, the promulgated schedule provides for demonstration submission 5 months after the end of the calendar year, the EPA expects that most submitting

agencies will have additional time to prepare documentation as we expect the majority of potential O<sub>3</sub>-related exceptional events to occur during the warmer months (*e.g.*, March through October). Additionally, the EPA will soon propose rule revisions to the 2007 Exceptional Events Rule and will release through a **Federal Register** Notice of Availability a draft guidance document to address Exceptional Events Rule criteria for wildfires that could affect O<sub>3</sub> concentrations. We expect to promulgate Exceptional Events Rule revisions and finalize the new guidance document before the October 2016 date by which states, and any tribes that wish to do so, are required to submit their initial designation recommendations for the revised O<sub>3</sub> NAAQS. Considered together, the EPA believes the exceptional events scheduling dates promulgated in this action, the upcoming Exceptional Events Rule revisions, the forthcoming guidance, and the existing guidance and examples of submitted demonstrations currently on the EPA's exceptional events Web site at <http://www2.epa.gov/air-quality-analysis/treatment-data-influenced-exceptional-events>, will help air agencies submit information in a timely manner.

Applying the "delta schedule" promulgated in this action for air quality data collected in 2013 through 2014 that could be influenced by exceptional events and be considered during the initial area designations process for the revised O<sub>3</sub> NAAQS, results in extending to July 1, 2016, the otherwise applicable generic deadlines of July 1, 2014, and July 1, 2015, respectively, for flagging data and providing an initial description of an event (40 CFR 50.14(c)(2)(iii)). The schedule promulgated in this action also results in a July 1, 2016, date for flagging data and providing an initial description of an event for air quality data collected in 2015. The July 1, 2016, date for data collected in 2015 is the same as that which would apply under the existing generic deadline in the 2007 Exceptional Events Rule. Under the schedule promulgated in this action, October 1, 2016 is the deadline for submitting exceptional events demonstrations for data years 2013 through 2015. As noted previously, under the schedule promulgated in this action, affected air agencies would need to flag, submit initial event descriptions and submit demonstrations for exceptional events occurring in 2016 by May 31, 2017. The EPA believes these revisions will provide adequate time for air agencies to review potential O<sub>3</sub>

exceptional events influencing compliance with the revised O<sub>3</sub> NAAQS, to notify the EPA by flagging the relevant data and providing an initial event description in AQS, and to submit documentation to support exceptional events demonstrations. The schedule revisions promulgated in this action will also allow the EPA to consider and act on the submitted information during the initial area designation process.

While the EPA will make every effort to designate areas for any new or revised NAAQS on a 2-year schedule, the EPA recognizes that under some circumstances we may need up to an additional year for the designations process to ensure that air agencies and the EPA base designations decisions on complete and sufficient information. The promulgated schedule accounts for the possibility that the EPA might announce after promulgating a new or revised NAAQS that we are extending the designations schedule beyond 2 years using authority provided in CAA section 107(d)(B)(i). If the EPA determines that we will follow a 3-year designation schedule, the deadline is 2 years and 7 months after promulgation of a new or revised NAAQS for states to flag data influenced by exceptional events, submit initial event descriptions and submit exceptional events demonstrations for the last year of data that will be used in the designations (*e.g.*, if the EPA were to designate areas in October 2018, the exceptional events submittal deadline for 2017 data would be May 31, 2018). If the EPA notifies states and tribes of a designations schedule between 2 and 3 years, the deadline for states to flag data affected by exceptional events, submit initial event descriptions, and submit exceptional events demonstrations associated with data from the last year to be considered would be 5 months prior to the date specified for designation decisions.

Therefore, using the authority provided in CAA section 319(b)(2) and in the 2007 Exceptional Events Rule at 40 CFR 50.14(c)(2)(vi), the EPA is modifying the schedule for flagging data and submitting exceptional events demonstrations 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 5. As we did in the O<sub>3</sub> NAAQS proposal, we are also providing Table 6 to illustrate how the promulgated schedule might apply to the designations process for the revised O<sub>3</sub> NAAQS and to designations

<sup>216</sup> See Section VIII.B for additional detail on the initial area designations process for the revised O<sub>3</sub> NAAQS.

processes for other future new or revised NAAQS. <sup>217</sup> Additionally, in conjunction with promulgating exceptional events	schedules for initial area designations for new or revised NAAQS, the EPA, as proposed, is removing obsolete regulatory language in 40 CFR	50.14(c)(2)(iv) and (v) and 40 CFR 50.14(c)(3)(ii) and (iii) associated with exceptional events schedules for all historical standards.
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TABLE 5—SCHEDULE FOR FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA INFLUENCED BY EXCEPTIONAL EVENTS FOR USE IN INITIAL AREA DESIGNATIONS

Exceptional events/Regulatory action	Exceptional events deadline schedule <sup>d</sup>
Flagging and initial event description deadline for data years 1, 2 and 3 <sup>a</sup> .	If state and tribal initial designation recommendations for a new/revised NAAQS are due August through January, then the flagging and initial event description deadline will be the July 1 prior to the recommendation deadline. If state and tribal recommendations for a new/revised NAAQS are due February through July, then the flagging and initial event description deadline will be the January 1 prior to the recommendation deadline.
Exceptional events demonstration submittal deadline for data years 1, 2 and 3 <sup>a</sup> .	No later than the date that state and tribal recommendations are due to the EPA.
Flagging, initial event description and exceptional events demonstration submittal deadline for data year 4 <sup>b</sup> and, where applicable, data year 5 <sup>c</sup> .	By the last day of the month that is 1 year and 7 months after promulgation of a new/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/revised NAAQS. b. If the EPA notifies the state/tribe that it intends to complete the initial area designations process according to a schedule between 2 and 3 years, the deadline is 5 months prior to the date specified for final designations decisions in such EPA notification.

<sup>a</sup> Where data years 1, 2, and 3 are those years expected to be considered in state and tribal recommendations.  
<sup>b</sup> Where data year 4 is the additional year of data that the EPA may consider when it makes final area designations for a new/revised NAAQS under the standard designations schedule.  
<sup>c</sup> Where data year 5 is the additional year of data that the EPA may consider when it makes final area designations for a new/revised NAAQS under an extended designations schedule.  
<sup>d</sup> 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 as specified in 40 CFR 58.15(a)(2). 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 first 8 months of the calendar year. Data flagging, initial event description and exceptional events demonstration deadlines for "early certified" data will follow the deadlines for "year 4" and "year 5" data.

<sup>217</sup> The range of dates identified in Table 6 is illustrative of the dates for the revised O<sub>3</sub> NAAQS. Users could increment these dates by any constant number (for example by 6 years for a hypothetical NAAQS promulgated in 2021) to develop a table with dates relevant to NAAQS promulgated in the future.

Table 6. Examples by Month of Applying the Promulgated Revised Schedule for Flagging and Documentation Submission for Data Influenced by Exceptional Events for Use in Initial Area Designations

Exceptional Events / Regulatory Action	Exceptional Events Deadline Schedule <sup>c</sup>	Month of NAAQS Promulgation, State and Tribal Recommendation, and Final Designations													
		Oct	Nov	Dec	Jan	Feb	Mar	Apr	May <sup>d</sup>	Jun <sup>d</sup>	Jul <sup>d</sup>	Aug <sup>d</sup>	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	
Flagging and initial event description deadline for data years 1, 2, and 3. <sup>a</sup>	If state and tribal initial designation recommendations for a new/revised NAAQS are due August through January, then the flagging and initial event description deadline will be the July 1 prior to the recommendation deadline. If state and tribal recommendations for a new/revised NAAQS are due February through July, then the flagging and initial event 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 2013, 2014, 2015)	Jan 1, 2017 (data years 2013, 2014, 2015)	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 events demonstration submittal deadline for data years 1, 2, and 3. <sup>a</sup>	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 2013, 2014, 2015)	by July 2017 (data years 2013, 2014, 2015)	by Aug 2017 (data years 2013, 2014, 2015)	by Sep 2017 (data years 2013, 2014, 2015)	by Oct 2017 (data years 2013, 2014, 2015)	
AQS quality assurance 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	
Flagging, initial event description and exceptional events demonstration submittal deadline for data year 4 <sup>b</sup> and, where applicable, data year 5. <sup>c</sup>	By the last day of the month that is 1 year and 7 months after promulgation of a new/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/revised NAAQS. b. If the EPA notifies the state/tribe that it intends to complete the initial area designations process according to a schedule between 2 and 3 years, 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 (data year 2017)	by Sep 30, 2017 (data year 2016) and potentially (data year 2017)	by Oct 31, 2017 (data year 2016) and potentially (data year 2017)	by Nov 30, 2017 (data year 2016) and potentially (data year 2017)	by Dec 31, 2017 (data year 2016) and potentially (data year 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)	
<b>State &amp; Tribal Recommendations to EPA</b>		<b>Oct 2016</b>	<b>Nov 2016</b>	<b>Dec 2016</b>	<b>Jan 2017</b>	<b>Feb 2017</b>	<b>Mar 2017</b>	<b>Apr 2017</b>	<b>May 2017</b>	<b>June 2017</b>	<b>July 2017</b>	<b>Aug 2017</b>	<b>Sep 2017</b>	<b>Oct 2017</b>	
<b>EPA notifies States/Tribes of intended modifications to recommendations (EPA sends 120-day letters)</b>		<b>June 2017</b>	<b>July 2017</b>	<b>Aug 2017</b>	<b>Sep 2017</b>	<b>Oct 2017</b>	<b>Nov 2017</b>	<b>Dec 2017</b>	<b>Jan 2018</b>	<b>Feb 2018</b>	<b>Mar 2018</b>	<b>Apr 2018</b>	<b>May 2018</b>	<b>June 2018</b>	
<b>Administrator Promulgates Final Designations</b>		<b>Oct 2017</b>	<b>Nov 2017</b>	<b>Dec 2017</b>	<b>Jan 2018</b>	<b>Feb 2018</b>	<b>Mar 2018</b>	<b>Apr 2018</b>	<b>May 2018</b>	<b>June 2018</b>	<b>July 2018</b>	<b>Aug 2018</b>	<b>Sep 2018</b>	<b>Oct 2018</b>	

<sup>a</sup> Where data years 1, 2, and 3 are those years expected to be considered in state and tribal recommendations.

<sup>b</sup> Where data year 4 is the additional year of data that the EPA may consider when it makes final area designations for a new/revised NAAQS under the standard designations schedule.

<sup>c</sup> Where data year 5 is the additional year of data that the EPA may consider when it makes final area designations for a new/revised NAAQS under an extended designations schedule.

<sup>d</sup> 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 as specified in 40 CFR 58.15(a)(2). 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 first 8 months of the calendar year. Data flagging, initial event description and exceptional events demonstration deadlines for "early certified" data will follow the deadlines for "year 4" and "year 5" data.

## VI. Ambient Monitoring Related to O<sub>3</sub> Standards

### A. Background

The EPA proposed to revise the state-by-state O<sub>3</sub> monitoring seasons; the PAMS monitoring requirements; the FRM for measuring O<sub>3</sub>; and the FEM performance requirement specifications for automated O<sub>3</sub> analyzers. The EPA also proposed to make additional minor changes to the FEM analyzer performance testing requirements for NO<sub>2</sub> and particulate matter in part 53.

The EPA is finalizing changes to the length of the required O<sub>3</sub> monitoring season for 32 states and the District of Columbia. Section VI.B of this preamble provides an overview of the proposed changes to the length of the required O<sub>3</sub> monitoring seasons, a summary of significant public comments and our responses, and a summary of the final decisions made to the O<sub>3</sub> monitoring seasons for each state.

The EPA is finalizing 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 PAMS program and current monitoring requirements, a summary of the proposed changes to the PAMS requirements, a summary of significant public comments and our responses, and a summary of the changes to the PAMS requirements in this final rule.

The EPA is finalizing changes to the FRM for O<sub>3</sub> in Section VI.D of this preamble and to the associated FEM performance requirement specifications for automated O<sub>3</sub> analyzers in Section VI.E. A summary of significant public comments and our responses are provided and a summary of the final changes to the FRM and FEM requirements in this final rule. The EPA is also finalizing minor additional changes to Part 53 including conforming changes to the FEM performance testing requirements in Table B-1 and Figure B-5 for NO<sub>2</sub>; 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 in part 53.14; and removing an obsolete provision for manufacturers to submit Product Manufacturing Checklists for fine and coarse particulate matter monitors in part 53.9.

### B. Revisions to the Length of the Required O<sub>3</sub> Monitoring Seasons

Unlike the ambient monitoring requirements in 40 CFR part 58 for other criteria pollutants that mandate year-round monitoring at State and Local Air Monitoring Stations (SLAMS), O<sub>3</sub> monitoring is only required during the

seasons of the year that are conducive to O<sub>3</sub> formation. These seasons vary in length from place-to-place as the conditions conducive to the formation of O<sub>3</sub> (*i.e.*, seasonally-dependent factors such as ambient temperature, strength of solar insolation, and length of day) differ by location. In some locations, conditions conducive to O<sub>3</sub> formation are limited to the summer months of the year. In other states with warmer climates (*e.g.*, California, Nevada, and Arizona), the currently required O<sub>3</sub> season is year-round. Elevated levels of winter-time O<sub>3</sub> have also been measured in some western states where precursor emissions can interact with sunlight off the snow cover under very shallow, stable boundary layer conditions (U.S. EPA 2013).

The EPA has determined that the proposed lengthening of the O<sub>3</sub> monitoring seasons in 32 states and the District of Columbia is appropriate. Ambient O<sub>3</sub> concentrations in these areas could approach or exceed the level of the NAAQS, more frequently and during more months of the year compared with the current season lengths. It is important to monitor for O<sub>3</sub> during the periods when ambient concentrations could approach the level of the NAAQS to ensure that the public is informed when exposure to O<sub>3</sub> could reach or has reached a level of concern.

The EPA completed an analysis to address whether extensions of currently required monitoring seasons are appropriate (Rice, 2014). In this analysis, we used all available data in AQS, including data from monitors that collected O<sub>3</sub> data year-round during 2010–2013. More than half of O<sub>3</sub> monitors are voluntarily operated on a year-round basis by monitoring agencies. We determined the number of days where one or more monitors had a daily maximum 8-hour O<sub>3</sub> average equal to or above 0.060 ppm in the months outside each state's current O<sub>3</sub> monitoring season and the pattern of those days in the out-of-season months. We believe that a threshold of 0.060 ppm, taking into consideration reasonable uncertainty, serves as an appropriate indicator of ambient conditions that may be conducive to the formation of O<sub>3</sub> concentrations that approach or exceed the NAAQS. We also considered regional consistency, particularly for those states with little available data. We note that seasonal O<sub>3</sub> patterns vary year-to-year due primarily to highly variable meteorological conditions conducive to the formation of elevated O<sub>3</sub> concentrations early or late in the season in some years and not others. The EPA believes it is important that O<sub>3</sub> monitors operate during all

periods when there is a reasonable possibility of ambient levels approaching the level of the NAAQS.

Basing O<sub>3</sub> monitoring season requirements on the goal of ensuring monitoring when ambient O<sub>3</sub> levels approach or exceed the level of the 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<sup>218</sup> and to support comparisons of an area's air pollution levels to the NAAQS. The operation of O<sub>3</sub> monitors during periods of time when ambient levels approach or exceed the level of the NAAQS ensures that unusually sensitive people and sensitive groups are alerted to O<sub>3</sub> levels of potential health concern allowing them to take precautionary measures. The majority of O<sub>3</sub> monitors in the U.S. report to AIRNOW,<sup>219</sup> 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<sub>3</sub> forecasting, and the verification of real-time air quality forecast models.

#### 1. Proposed Changes to the Length of the Required O<sub>3</sub> Monitoring Seasons

The EPA proposed to extend the length of the required O<sub>3</sub> monitoring season in 32 states and the District of Columbia. The proposed changes were an increase of one month for 22 states (Connecticut, Delaware, Idaho, Illinois, Iowa, Kansas, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Texas (northern portion only), Virginia, and West Virginia) and the District of Columbia, 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 proposed 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. We proposed lengthening the required season in the northern part of Texas (AQCR 022, 210,

<sup>218</sup> Public reporting requirements are detailed in 40 CFR part 58 Appendix G, Uniform Air Quality Index (AQI) and Daily Reporting.

<sup>219</sup> See <http://airnow.gov/>.

211, 212, 215, 217, and 218) by one month and leaving the year-round O<sub>3</sub> season in the southern part of Texas (AQCRs 106, 153, 213, 214, and 216) unchanged. No changes were proposed for the AQCRs in Louisiana. As noted earlier, in a few states with limited available data and few exceedance days outside the currently-required season (Iowa, Missouri, and West Virginia), the proposed changes were made by considering supporting information from the surrounding states. These changes involved the proposed addition of one month (March) to the currently-required O<sub>3</sub> seasons for these states.

The EPA also proposed that O<sub>3</sub> monitors at all National Core Multipollutant Monitoring Stations (NCore) be operated year-round, January through December, regardless of the length of the required O<sub>3</sub> season for the remainder of the SLAMS within each state.

We noted that the EPA Regional Administrators have previously approved deviations from the required O<sub>3</sub> monitoring seasons as allowed by paragraph 4.1(i) of 40 CFR part 58, Appendix D. We proposed to retain the rule language permitting such deviations from the required O<sub>3</sub> monitoring seasons, but note that finalized changes to O<sub>3</sub> monitoring season requirements would revoke all existing Regional Administrator-granted waiver approvals. As appropriate, monitoring agencies could seek new approvals for seasonal deviations. Any seasonal 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.

Given the timing of the final rulemaking and any associated burden on state/local monitoring agencies to implement the extended O<sub>3</sub> seasons, we proposed that implementation of the revised O<sub>3</sub> seasons would become effective at SLAMS (including NCore sites) on January 1, 2017. We solicited 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<sub>3</sub> season.

## 2. Comments on the Length of the Required O<sub>3</sub> Monitoring Seasons

We received several comments on the proposed revisions to O<sub>3</sub> monitoring seasons. Several commenters supported the proposed O<sub>3</sub> season length changes and agreed that O<sub>3</sub> monitoring seasons should reflect the times of year when O<sub>3</sub> may approach or exceed the level of the

NAAQS. A few commenters noted the complexities that would arise in the implementation of multi-state planning agreements if states that shared an MSA had different required O<sub>3</sub> monitoring seasons. Two state agencies that supported season length changes also recommended changes to neighboring states' O<sub>3</sub> seasons. New York recommended that Connecticut's proposed O<sub>3</sub> season be further extended (adding the month of October) to match the proposed season in New York (March–October) because they share a major MSA and nonattainment area, and the highest design value monitor in the nonattainment area is often in Connecticut. The results from the EPA's analysis did not support the addition of October for Connecticut. The EPA recognizes that there may be value in having a consistent O<sub>3</sub> season across multi-state planning areas. We recommend that monitoring agency representatives from New York and Connecticut contact their respective EPA Regional Office to jointly develop a monitoring plan to provide coverage of the MSA for a longer period of time. Consistent with the results from the EPA's analysis and consistent with our proposal, the EPA is finalizing the March–October season in New York and the March–September season in Connecticut.

Although no changes were proposed for Arkansas, the Arkansas Department of Environmental Quality recommended that the O<sub>3</sub> season in the nonattainment area that includes Crittenden County, Arkansas (March–November) be consistent with the O<sub>3</sub> seasons in Tennessee (March–October) and Mississippi (March–October) by either shortening the O<sub>3</sub> season in Arkansas or lengthening the O<sub>3</sub> season by one month in Tennessee and Mississippi. Based on the results from the EPA's analysis and consistent with our proposal, the EPA is not finalizing any changes to the current O<sub>3</sub> seasons in Arkansas, Tennessee, or Mississippi. There is currently one monitor operating in Crittenden County. We recommend that Arkansas work with their EPA Regional Administrator to consider a waiver for the monitor(s) in Crittenden County to allow a deviation (shortened season) from the required O<sub>3</sub> season if the agency demonstrates that such a deviation is appropriate for consistency in the nonattainment area.

Two commenters noted the need to extend seasons to capture wintertime O<sub>3</sub> events. One commenter urged the EPA to extend monitoring to year-round in the intermountain west (specifically Wyoming) to adequately capture summer and winter O<sub>3</sub> problem days

and noted especially two monitors in the Pinedale area of Wyoming that should be operated year-round. The EPA's analysis showed that there were no days that were  $\geq 0.060$  ppm in Wyoming for the months of October–December and that the Wyoming Department of Environmental Quality is currently operating about 70% of their O<sub>3</sub> monitors year-round including all O<sub>3</sub> monitors in Sublette County, which includes the Pinedale area. Another commenter supported lengthening the seasons for states in the western U.S. where wintertime O<sub>3</sub> could be an issue in light of the unique and growing O<sub>3</sub> pollution problems caused by oil and gas development activities. They also recommended that the EPA expand the O<sub>3</sub> monitoring season to year-round for North Dakota, South Dakota, and Montana beyond what was proposed. The number of observed days that were  $\geq 0.060$  ppm in the months outside the season proposed for these states (one day for North Dakota and no days observed for South Dakota and Montana) do not support a further extension to the length of the O<sub>3</sub> monitoring season beyond what was proposed. These states are already operating a large percentage of their monitors year-round (89% in North Dakota, 100% in South Dakota, and 78% in Montana). The EPA is finalizing the seasons as proposed in Wyoming (January–September), North Dakota (March–September), South Dakota (March–October), and Montana (April–September). The EPA encourages these states to continue year-round operation of their monitors to determine what areas are affected by elevated levels of winter-time O<sub>3</sub>.

The commenters who opposed lengthening the O<sub>3</sub> monitoring seasons noted concerns with the threshold (0.060 ppm) used as the basis for the changes and the length of time (2010–2013) for which ambient data were retrieved and analyzed. Many of those with concerns recommended that levels in the proposed range (e.g., 0.065 ppm or 0.070 ppm) or the current NAAQS level of 0.075 ppm be used as the appropriate threshold for determining the O<sub>3</sub> season. With regard to the 0.060 ppm threshold used, this value is consistent with the 85 percent threshold used to require additional O<sub>3</sub> monitoring based on Appendix D requirements, which include the MSA population and design value.<sup>220</sup> As noted previously, year-to-year variability occurs in seasonal O<sub>3</sub> patterns based on highly variable and unpredictable meteorological

<sup>220</sup> See 40 CFR part 58, appendix D, Table D–2.



conditions, which can support the formation of early or late season elevated O<sub>3</sub> concentrations in some years and not in other years. This threshold serves as an appropriate indicator of ambient conditions that may be conducive to the formation of O<sub>3</sub> concentrations that approach or exceed the level of the NAAQS.

Certain logistical complexities were noted if longer seasons were required, including site access during winter and the challenge of getting the monitoring equipment ready in time. Four states noted concerns with operator safety and anticipated their inability to access sites due to early spring snowfall. The EPA agrees that site access could be an issue depending on weather conditions and notes that specific site monitoring season deviations may be appropriate. We suggest that this be addressed through the monitoring season waiver process with the EPA Regional Administrator. 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 AQS.

Several commenters had concerns about the additional cost and resources needed to expand the O<sub>3</sub> monitoring seasons. There was some disagreement with the EPA's total annual average cost estimate of \$230,000 which took into account the number of O<sub>3</sub> monitors already operating year-round across the country. Commenters noted specifically that the proposed extension of required monitoring seasons would increase operational costs and potentially impact the resources available for other monitoring efforts. The added cost of operating O<sub>3</sub> monitors over a longer period was noted by some commenters, referencing both the cost of staff to operate the monitors, as well as the additional wear and tear those O<sub>3</sub> monitors would experience over a longer operational period. They noted that extending their required monitoring season by adding the month of March would increase staffing requirements for monitor operation and quality assurance. They also noted that the life expectancy of equipment would be reduced due to increased wear and tear. The EPA acknowledges that operational costs for O<sub>3</sub> monitoring networks will incrementally increase in states where required seasons have been lengthened. We encourage monitoring agencies to review available technology and operational procedures to institute practices that could potentially reduce such costs, such as the automation of quality control and calibration checks and remote access to evaluate monitor operations. As noted earlier, all states

operated at least a portion of their O<sub>3</sub> monitoring network outside of the required O<sub>3</sub> season during the 2010–2013 data period and reported the data to AQS. In addition, many states are operating more than the minimum number of monitors required to support the basic monitoring objectives described in 40 CFR part 58, Appendix D. Some states have a large percentage of their total O<sub>3</sub> monitors operating outside the currently-required O<sub>3</sub> season and some states have a small percentage. In situations where states are already operating a large number of their O<sub>3</sub> monitors outside their current O<sub>3</sub> season, the actual cost increase will be less. In cases where states have a small number of monitors operating outside their current O<sub>3</sub> season, in addition to automation and remote access, those states could investigate with their Regional Administrator the process in 40 CFR part 58.14 for reducing the total number of operating monitors that are above the number required by 40 CFR, part 58, appendix D to offset the cost of extending the O<sub>3</sub> monitoring season in their state.

Two commenters had concerns about the 4-year period of time evaluated in the EPA's analysis and noted that the 4-year period of time evaluated does not take into account meteorological anomalies and other weather induced situations and is not consistent with the 3 years used to calculate design values. One state agency's comments referenced their own analysis showing concentrations going back 20 years. They noted that 2010 was an unusual year and inclusion of such an unusual year in the 4-year period (2010–2013) of the EPA's analysis provides too much weight on those data. As noted earlier, year-to-year variability occurs in seasonal O<sub>3</sub> patterns based on variable meteorological conditions and given the impracticality of forecasting such conditions that affect O<sub>3</sub> photochemistry, the EPA believes it is important that O<sub>3</sub> monitors operate when there is a reasonable possibility of ambient levels approaching the level of the NAAQS. Another state agency commented that 4 years appeared to be an unusual number of years given that design values are based on 3 years. To support the proposed rule in 2014, the EPA's analysis of O<sub>3</sub> seasons began in 2013. At that time the EPA's analysis considered the most recent 3 years of certified data (2010–2012) and updated the analysis to add a fourth year (2013) when the data were quality-assured, certified, and available in AQS. We used 4 years of data, including the most recent year (2013) to include an

additional year of potentially-variable meteorological conditions to propose changes to the seasons. The EPA treated all years equally and did not put any more weight on the 2010 data than any of the other years used in the analysis. The EPA believes that using recently-available data across multiple years to capture varying meteorological conditions was appropriate to support the decisions on extending the O<sub>3</sub> seasons. One commenter disagreed with the EPA's definition of year-round (at least 20 daily observations in all 12 months of at least 1 year of the 4-year period). The definition of year-round was used to estimate the number of monitors being operated outside a state's required O<sub>3</sub> season and also used for the EPA's Information Collection Request (ICR). All available data in AQS were used for the O<sub>3</sub> season analysis, including data from year-round monitors.

Two commenters noted that "regional consistency" is not a scientific reason and is not needed for making changes to the O<sub>3</sub> seasons. One commenter noted that significant geographical, meteorological and demographic differences exist between neighboring states that may not warrant identical monitoring seasons. The EPA notes that regional consistency was considered, but only important for a few states where little data were available and the neighboring states had more available data and a sufficient number of days that were  $\geq 0.060$  ppm to support the proposed O<sub>3</sub> season changes. Regional consistency was not important for other states.

Some commenters expressed support for the proposed requirement that NCore O<sub>3</sub> sites operate year-round. They questioned whether data from NCore stations outside the O<sub>3</sub> season will be used for designations and requested that the EPA exclude those data from the designations process. Consistent with the designations process for all criteria pollutants, the states, tribes, and the EPA use all data available in AQS that meet the quality assurance requirements in 40 CFR part 58, Appendix A for the designations process. Given that O<sub>3</sub> data from NCore stations will meet these requirements, there is no rational basis for excluding these data from comparison to the NAAQS. Accordingly, such data from NCore stations cannot be excluded and will be treated in a manner equivalent to all other O<sub>3</sub> data in AQS. The EPA expects that the highest O<sub>3</sub> values will occur during the required O<sub>3</sub> season; therefore, we don't anticipate that NCore data from the out-of-season months will contribute to the design value used in

the designations process. The EPA is finalizing the requirement for year-round O<sub>3</sub> monitoring at NCore stations.

The EPA Regional Administrators have previously approved deviations from the required O<sub>3</sub> 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<sub>3</sub> monitoring season without rulemaking. The EPA is retaining the rule language allowing such deviations from the required O<sub>3</sub> monitoring seasons without rulemaking. In the finalized revision to paragraph 4.1(i) of 40 CFR part 58, Appendix D, the EPA is clarifying the minimum considerations that should be taken into account when reviewing requests, and clarifying that changes to the O<sub>3</sub> seasons finalized in this rule revoke all previously approved seasonal deviations. The EPA clarifies that all O<sub>3</sub> season waivers will be revoked when this final rule becomes effective. We encourage monitoring agencies with existing waivers to engage their EPA Regions as soon as possible to evaluate whether new or continued waivers are appropriate given the level of the revised O<sub>3</sub> NAAQS.

We received three comments for and three comments against early implementation of the revised O<sub>3</sub> seasons by the start of the applicable O<sub>3</sub> season in each state by January 1, 2016. Those commenters in favor of early implementation of the revised O<sub>3</sub> seasons are already operating a large percentage of O<sub>3</sub> monitors year-round or outside the current O<sub>3</sub> monitoring season in their state. Those commenters against early implementation cited concerns with the need for additional time to implement the revised O<sub>3</sub> seasons, especially in areas where access in order to service and support the monitoring equipment may be problematic during winter weather conditions, and the undue burden on already constrained state resources. One commenter noted that given the date for the final rule (October 1, 2015) that there is insufficient time for public review of their annual monitoring network plan due July 1, 2015, for early implementation in 2016. The EPA encourages those agencies who are able to implement the O<sub>3</sub> season changes early to do so by the start of the applicable O<sub>3</sub> season in their state in 2016. However, taking into consideration the timing and potential burden on monitoring agencies, the EPA

is finalizing the requirement for implementing the revised O<sub>3</sub> seasons no later than the start of the applicable O<sub>3</sub> monitoring season in 2017, as proposed.

### 3. Final Decisions on the Length of the Required O<sub>3</sub> Monitoring Seasons

Final changes to the required O<sub>3</sub> monitoring seasons are summarized in this section as well as in revised Table D-3 in 40 CFR part 58, Appendix D.

Detailed state-by-state technical information has been placed in the docket to document the basis for the EPA's decision on each state. This information includes state-by-state maps and number of days that were  $\geq 0.060$  ppm; distribution charts of the number of days that were  $\geq 0.060$  ppm by month and state; and detailed information regarding AQS site IDs, dates and concentrations of all occurrences of the 8-hour daily maximum of at least 0.060 ppm between 2010 and 2013. Summaries have also been prepared for each state including the former and proposed O<sub>3</sub> monitoring seasons.

No changes to the required O<sub>3</sub> monitoring season were proposed or finalized for these states: Alabama, Alaska, Arizona, Arkansas, California, Georgia, Hawaii, Kentucky, Northern Louisiana (AQCR <sup>221</sup> 019, 022), Southern Louisiana (AQCR 106), Maine, Mississippi, Nevada, New Mexico, Oklahoma, Oregon, Tennessee, Southern Texas (AQCR 106, 153, 213, 214, 216), Vermont, Washington, Puerto Rico, Virgin Islands, Guam, and American Samoa. All existing O<sub>3</sub> season deviations or waivers are revoked.

Changes to the required O<sub>3</sub> monitoring seasons are finalized as follows for these states and the District of Columbia and all existing O<sub>3</sub> season deviations or waivers are revoked.

Colorado: Proposed addition of January, February, October, November, and December is finalized. The required season is revised to January–December.

Connecticut: Proposed addition of March is finalized, revising season to March–September.

Delaware: Proposed addition of March is finalized, revising season to March–October.

District of Columbia: Proposed addition of March is finalized, revising season to March–October.

Florida: Proposed addition of January, February, November, and December is finalized. The required season is revised to January–December.

Idaho: Proposed addition of April is finalized, revising season to April–September.

Illinois: Proposed addition of March is finalized, revising season to March–October.

Indiana: Proposed addition of March and October, revising season to March–October.

Iowa: Proposed addition of March is finalized, revising season to March–October.

Kansas: Proposed addition of March is finalized, revising season to March–October.

Maryland: Proposed addition of March is finalized, revising season to March–October.

Massachusetts: Proposed addition of March is finalized, revising season to March–September.

Michigan: Proposed addition of March and October is finalized, revising season to March–October.

Minnesota: Proposed addition of March is finalized, revising season to March–October.

Missouri: Proposed addition of March is finalized, revising season to March–October.

Montana: Proposed addition of April and May is finalized, revising season to April–September.

Nebraska: Proposed addition of March is finalized, revising season to March–October.

New Hampshire: Proposed addition of March is finalized, revising season to March–September.

New Jersey: Proposed addition of March is finalized, revising season to March–October.

New York: Proposed addition of March is finalized, revising season to March–October.

North Carolina: Proposed addition of March is finalized, revising season to March–October.

North Dakota: Proposed addition of March and April is finalized, revising season to March–September.

Ohio: Proposed addition of March is finalized, revising season to March–October.

Pennsylvania: Proposed addition of March is finalized, revising season to March–October.

Rhode Island: Proposed addition of March is finalized, revising season to March–September.

South Carolina: Proposed addition of March is finalized, revising season to March–October.

South Dakota: Proposed addition of March, April, May, and October is finalized, revising season to March–October.

Texas (Northern AQCR 022, 210, 211, 212, 215, 217, 218): Proposed addition of November is finalized, revising season to March–November.

Utah: Proposed addition of January, February, March, April, October,

<sup>221</sup> Air Quality Control Region.

November, and December is finalized. The required season is revised to January–December.

Virginia: Proposed addition of March is finalized, revising season to March–October.

West Virginia: Proposed addition of March is finalized, revising season to March–October.

Wisconsin: Proposed addition of March and April 1–15 is finalized, revising season to March–October 15.

Wyoming: Proposed addition of January, February, March, and removal of October is finalized, revising season to January–September.

Finally, we are finalizing the required O<sub>3</sub> monitoring season for all NCore stations to be year-round (January–December) regardless of the required monitoring season for the individual state in which the NCore station is located.

### C. Revisions to the PAMS Network Requirements

Section 182 (c)(1) of the CAA required the EPA to promulgate rules for enhanced monitoring of O<sub>3</sub>, NO<sub>x</sub>, and VOCs for nonattainment areas classified as serious (or above) to obtain more comprehensive and representative data on O<sub>3</sub> 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<sub>3</sub> precursors in tropospheric O<sub>3</sub> formation and control. As a result of this study, 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<sub>3</sub> nonattainment area classified as serious, severe, or extreme (“PAMS areas”). As noted in the EPA’s Technical Assistance Document (TAD) for Sampling and Analysis of Ozone Precursors (U.S. EPA, 1998), the current objectives of the PAMS program are to: (1) Provide a speciated ambient air database that 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 volatile organic compounds (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 that is characteristic of source

emission impacts to be used in analyzing emissions inventory issues and corroborating progress toward attainment; (4) provide ambient data measurements that 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 requirements called for two to five fixed sites per PAMS 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<sub>3</sub> concentration (Type 3), and extreme downwind (Type 4) sites. Each PAMS site was required to measure O<sub>3</sub>, nitrogen oxide (NO), NO<sub>2</sub>, 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 61236), the EPA revised the PAMS requirements to only require two sites per PAMS area. 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<sub>3</sub> nonattainment areas; the changes also gave 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<sub>3</sub> standards. 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<sub>3</sub> 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<sub>3</sub> 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; however, PAMS requirements were identified as requirements that had to be

retained in the anti-backsliding provisions 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<sub>3</sub> standards 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 Northeast U.S. and California with relatively limited coverage in the rest of the country (Cavender, 2014).

The first PAMS sites began operation in 1994, and have been in operation for over 20 years. Since the start of the program, there have been many changes to the nature and scope of the O<sub>3</sub> problem in the U.S. as well as to our understanding of it. The O<sub>3</sub> standards has been revised multiple times since the PAMS program was first implemented. On July 18, 1997, the EPA revised the O<sub>3</sub> NAAQS to a level of 0.08 parts per million (ppm), with a form based on the 3-year average of the annual fourth-highest daily maximum 8-hour average O<sub>3</sub> concentration. On March 28, 2008 (73 FR 16436), the EPA revised the O<sub>3</sub> standards 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<sub>3</sub> concentration. These changes in the level and form of the O<sub>3</sub> NAAQS, along with notable decreases in O<sub>3</sub> levels in most parts of the U.S., have changed the landscape of O<sub>3</sub> NAAQS violations in the U.S. At the time of the first round of designations for the 8-hour standards (June 15, 2005), only 5 areas were classified as serious or above for the 8-hour standards as compared to 22 areas that were classified as serious or above for the 1-hour standards. While the number of serious and above areas decreased, the number of nonattainment areas remained nearly the same. In addition to the change in the landscape of O<sub>3</sub> nonattainment issues, much of the equipment used at PAMS sites is outdated 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 to simplify procedures and improve data quality. For these reasons, the EPA determined that it would be appropriate to re-evaluate the PAMS program as explained below.

In 2011, 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 the Clean Air Science Advisory Committee (CASAC), 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<sub>3</sub> 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, 2011f). 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. Specific advice obtained from the CASAC AMMS and the MSC that was considered in making the proposed changes to the PAMS requirements is discussed in the appropriate sections below.

Based on the findings of the PAMS evaluation and the consultations with the CASAC AMMS and NACAA MSC, the EPA proposed 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) meteorology measurements. The following paragraphs summarize the proposed changes, the comments received, and the final changes and supporting rationale.

#### 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, 2011f), 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<sub>3</sub> 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<sub>3</sub> 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, 2011f) noted the spatial coverage issue and advised that the EPA should consider requiring PAMS measurements in areas in addition to “areas classified as serious and above for the O<sub>3</sub> NAAQS to improve spatial coverage.” The EPA also agrees with CASAC and NACAA that the PAMS requirements should be revised to provide monitoring agencies greater flexibility in meeting local objectives.

The EPA proposed changes to the network design requirements to better serve both national and local objectives. The EPA proposed a two part network design. The first part of the design included a network of fixed sites (“required PAMS sites”) intended to support O<sub>3</sub> model development and the tracking of trends of important O<sub>3</sub> precursor concentrations. The second part of the network design required states with O<sub>3</sub> non-attainment areas to develop and implement Enhanced Monitoring Plans (EMPs) which were intended to allow monitoring agencies the needed flexibility to implement additional monitoring capabilities to suit the needs of their area.

To implement the fixed site portion of the network design, the EPA proposed to require PAMS measurements at any existing NCore site in an O<sub>3</sub> nonattainment area in lieu of the current PAMS network design requirements.<sup>222</sup>

<sup>222</sup> The EPA noted that the proposed change would expand the PAMS applicability beyond that required in 182(c)(1) of the CAA. Thus, in this final

The NCore network is a multi-pollutant monitoring network consisting of 80 sites (63 urban, 17 rural) sited in typical neighborhood scale locations and supports multiple air quality objectives including some of the objectives of the PAMS program including the development and evaluation of photochemical models (including both PM<sub>2.5</sub> and O<sub>3</sub> models), development and evaluation of control strategies, and the tracking of regional precursor trends.

The EPA recognized 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<sub>3</sub> 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 also proposed to provide the EPA Regional Administrator the authority to approve an alternative location for a required PAMS site where appropriate. The EPA also solicited comments on alternative frameworks using other benchmarks such as attainment status or population to ensure an appropriately sized fixed PAMS monitoring network. The EPA received several comments on the proposed changes to the network design, primarily from state and local monitoring agencies. The following paragraphs summarize the major comments made on the proposed network design, our response, and final network design requirements.

Most commenters agreed with the need to revise the existing network design. One commenter agreed that “requiring PAMS monitoring at already existing NCore locations will benefit national and local objectives to understand ozone formation and would also provide significant cost efficiencies.” Another commenter stated that they supported the proposed changes, “especially the flexibility provided by EMPs designed to meet local objectives and achieve a better understanding of photochemical precursors.” Another commenter supporting the changes stated that the “proposed network revision will provide states the flexibility to use their resources effectively.” One commenter stated that the proposed changes “reflect a more efficient use of state and local monitoring resources by availing

rule, the EPA is relying on the authority provided in Sections 103(c), 110(a)(2)(B), 114(a) and 301(a)(1) of the CAA to expand the PAMS applicability to areas other than those that are serious or above O<sub>3</sub> nonattainment.

monitoring agencies of existing NCore infrastructure to fulfill PAMS requirements.”

A number of concerns were also raised with the proposed network design. Several commenters stated that the proposal “would drastically reduce the PAMS network in the Northeast.” One commenter stated that “this is not acceptable for the Northeast and Mid-atlantic Corridor, which requires monitoring of the complex transport from multiple large metropolitan areas in the region.” One commenter recognized that the EPA had intended to allow states to use EMPs to address upwind and downwind data needs, but raised concerns that states with historically important upwind and downwind sites in the Ozone Transport Region <sup>223</sup> (OTR) may not be required to develop an EMP since those sites would be in states that are attaining the O<sub>3</sub> NAAQS. One commenter suggested that “the EPA consider the entire OTR when designing a PAMS network rather than pockets of nonattainment areas in the region.” The EPA agrees that the reduction of sites in the OTR is a potential issue and that many important existing PAMS sites would not be part of the required PAMS sites based on the proposed network design. As noted by several commenters, the EPA intended the state directed EMPs to give states flexibility in determining data needed to understand local O<sub>3</sub> formation, including transport in the Northeast. However, the EPA also agrees that as proposed many states in the OTR would not be required to develop EMPs and, therefore, may not be provided PAMS resources. To address these concerns and ensure adequate network coverage in the OTR, the EPA is adding a requirement that all states in the OTR develop and implement an EMP regardless of O<sub>3</sub> attainment status. This change will help ensure that an EMP appropriate for the entire OTR can be implemented.

Concerns were raised by some states that existing NCore sites may not be the most appropriate location for making PAMS measurements. One commenter noted that their NCore site was inland but that their “most significant ozone problems occur along the shoreline due to transport along the lake”, and that “the NCore site cannot provide insight into these important lakeshore ozone processes.” Another commenter stated that “while it was laudable to leverage

sites where data is already being collected, it is unclear whether NCore sites adequately meet the objectives of the PAMS program”, and that “the current NCore network may not be adequate to depict boundary conditions or areas of maximum emissions.” One commenter stated that “in some nonattainment areas an NCore site may be an appropriate location for a PAMS monitor, but in other areas it would be preferable to install the PAMS monitoring in a location downwind of a source region where higher ozone exposures occur” and that “State and local boundaries should not be part of the network design criteria.” One commenter noted that while the EPA had proposed to allow waivers, it was unclear if waivers would be allowed where the alternative site was in a different CBSA or state than the required PAMS site. As stated in our proposal, the EPA recognizes that in some cases existing PAMS sites (or other sites) may be better suited to meet local and national data needs. For this reason, we had proposed to allow waivers in these situations. We do agree that it is appropriate in some cases to allow these waivers to cross CBSA and state boundaries. Therefore, we have added specific language to the final waiver provisions to clarify that waivers can be allowed to cross CBSA and state boundaries. Where a monitoring agency receives a waiver from siting a monitor in reliance on a monitor operated by a different monitoring agency (*e.g.*, across state lines), the waiver will be conditioned on the monitor being properly included in the other agency’s network plan, and operated in accordance with the requirements of Part 58, including the relevant appendices.

In addition to the concerns raised about closing important existing PAMS sites discussed above, some commenters raised concerns that many of the newly required PAMS sites would be in locations that were expected to attain the revised O<sub>3</sub> NAAQS soon after the new sites would be installed. One commenter noted that “requiring marginal nonattainment areas to install PAMS sites would result in a large undertaking in an area that would most likely be back in attainment at or around the time the PAMS site started collecting data.” One commenter stated that by tying the network requirement to NAAQS attainment “threatens to underserve areas that are very close to exceeding the revised ozone NAAQS and results in significant gaps in the spatial coverage of the PAMS network” and “has the potential to introduce

undesirable uncertainty on the size and spatial extent of the PAMS network over the long term.” Another commenter was concerned that the proposed network would be unstable, and would experience frequent changes as areas came into attainment or went out of attainment thus reducing the value of the data collected, and resulting in inefficient use of resources. One commenter noted that “a more stable monitoring network design will allow for the examination of trends from spatially robust, long running sites and will allow states to firmly establish the infrastructure costs.”

The EPA noted in the proposal that the size and locations of the proposed required PAMS network is sensitive to the level of the revised O<sub>3</sub> NAAQS and future O<sub>3</sub> concentrations. We recognize and agree that if current downward trends in O<sub>3</sub> concentrations continue, many initially required sites may no longer be required to make PAMS measurements soon after the sites were installed. Non-required sites could be closed, soon after being installed, at the state’s discretion. We agree this would result in an inefficient use of resources. We also note that if these sites were closed following a potential reclassification to attainment, the loss of those sites could lead to a network with poor spatial coverage. Therefore, the EPA is making changes to the proposed revisions to the network design to improve the stability of the fixed site network. As explained below, the final requirements are based on options for which we requested comments in the proposal and the comments we have received.

We requested comments on additional options to define the fixed PAMS network component of the new network design. These options were further discussed in a memorandum to the docket (Cavender, 2014). One option discussed was to require PAMS measurements at all NCore sites irrespective of the O<sub>3</sub> attainment status of the area. One commenter noted that “requiring PAMS monitoring at all NCore sites, regardless of ozone attainment status, provides the most spatially robust and stable monitoring network.” We noted that this requirement would result in a network of approximately 80 sites, which would be larger than the current network. In the supporting memorandum, we noted that a fixed network of 80 sites would strain existing resources and would not allow adequate resources to implement the state directed EMPs.

Another option discussed in the proposal included requiring PAMS measurements at NCore sites in O<sub>3</sub>

<sup>223</sup> Section 184(c) of the CAA establishes the OTR as comprised of the states of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Consolidated Metropolitan Statistical Area that includes the District of Columbia.

nonattainment areas with a population greater than 1,000,000. We noted that this option would result in a network of between 31 and 37 sites depending on the level of the revised O<sub>3</sub> NAAQS. We also noted that focusing the applicability of PAMS to those NCore sites in larger CBSAs would still provide the desired improvement in geographic distribution while reducing the number of required sites down to a level that would provide sufficient resources to implement the state-directed EMP portion of the network. One commenter stated that they “supported a 1,000,000 population threshold because it would help prioritize resources to areas based on the greatest human health impacts.” In addition, a number of commenters, while not commenting on the need for a population limit, did raise concerns about their ability to acquire and retain staff with the necessary expertise to collect PAMS measurements in less urbanized areas. As with the proposed network design, we recognize that the total number of sites and the ultimate spatial coverage under this option is also sensitive to changes in O<sub>3</sub> concentrations. If current downward trends in O<sub>3</sub> concentrations continue, many initially required sites would not be required soon after they were installed. As with the proposed option, this option could result in an unstable network resulting in an inefficient use of resources and inadequate spatial coverage to meet the network goals discussed above.

Upon further consideration and in response to the comments received, we are finalizing a network design that includes a requirement for states to make PAMS measurements at all NCore sites in CBSAs with a population of 1,000,000 people or more, irrespective of O<sub>3</sub> attainment status. We believe this requirement will result in an appropriately sized network (roughly 40 sites) that will provide adequate spatial coverage to meet national model evaluation needs (Cavender, 2015). Redundancy is greatly reduced while important network coverage is added in the midwest, southeast, and mountain west. The improved spatial coverage will also strengthen the EPA’s ability to track trends in precursor concentrations regionally.

Because the network requirement is not tied to attainment status, this final requirement will ensure network stability and allows for more efficient use of available resources. This final requirement also removes uncertainty as to applicability and aids planning and logistics involved with implementing the new requirements. Monitoring

agencies can determine the applicability of the fixed site requirements to their areas today, and begin to make plans for investments in equipment, shelter improvements, and staffing and training needs necessary to implement the fixed site requirements without having to wait for the designations process to be completed. In addition, this final requirement should alleviate concerns raised by monitoring agencies in more rural locations over the ability to attract and retain staff with the skills necessary to make PAMS measurements.

By adding the PAMS measurements to existing NCore sites, significant efficiencies can be obtained which should further reduce the costs of the fixed site network as NCore sites currently make many of the PAMS measurements. Furthermore, adding the additional PAMS measurements (*e.g.*, speciated VOCs, carbonyls, and mixing height) to existing NCore sites will improve our ability to assess other pollutants (*e.g.*, air toxics and PM<sub>2.5</sub>).

Although, as discussed in comment and summarized above, we believe there are good reasons for not tying the requirement for fixed PAMS sites to O<sub>3</sub> attainment status, we continue to believe that requiring PAMS measurements in areas that historically have had low O<sub>3</sub> concentrations is unlikely to provide data of significant value to warrant the expense and effort of making such measurements. Therefore, we have included a provision that would allow a monitoring agency to obtain a waiver, based on Regional Administrator approval, in instances where CBSA-wide O<sub>3</sub> design values are equal to or less than 85% of the 8-hour O<sub>3</sub> NAAQS and where the site is not considered an important upwind or downwind site for other nonattainment areas. The EPA selected 85% as the threshold for this waiver provision as it has been used historically to identify locations needing additional monitoring for both the O<sub>3</sub> and PM<sub>2.5</sub> NAAQS. The EPA will work with the monitoring agencies and the Regions to help ensure consistent implementation of this waiver provision.

The second part of the proposed PAMS network design included monitoring agency directed enhanced O<sub>3</sub> monitoring activities intended to provide data needed to understand an area’s specific O<sub>3</sub> issues. To implement this part of the PAMS network design, the EPA proposed to add a requirement for states with O<sub>3</sub> nonattainment areas to develop an EMP. The purpose of the EMP was to improve monitoring for ambient concentrations of O<sub>3</sub>, NO<sub>x</sub>, total

reactive nitrogen (NO<sub>y</sub>)<sup>224</sup>, VOC, and meteorology. The EPA suggested that types of activities that might be included in the state’s EMP could include additional PAMS sites (*e.g.*, upwind or downwind sites), additional O<sub>3</sub> and NO<sub>x</sub> monitoring, ozonesondes or other aloft measurements, rural measurements, mobile PAMS sites, additional meteorological measurements, and episodic or intensive studies. The intent of the EMPs is to allow monitoring agencies flexibility in determining and collecting the information they need to understand their specific O<sub>3</sub> problems.

We received comments on the proposed requirement for an EMP in states with O<sub>3</sub> nonattainment areas. Most comments supported the requirement, but other comments raised a number of concerns. A number of commenters questioned the need for EMPs in Marginal and Moderate O<sub>3</sub> nonattainment areas. They noted that in most cases, Marginal O<sub>3</sub> nonattainment areas were expected to come into compliance without state-specific controls. One commenter stated that “nonattainment areas projected to attain the standard without additional state-level actions may not need the PAMS resources and additional monitoring to develop a better understanding of their ozone issues.” One commenter noted that “marginal ozone nonattainment areas are given only a few requirements because it is assumed that the areas will reach attainment within three years.” Another commenter stated “requiring enhanced monitoring for any marginal or moderate area should only be implemented where such analyses show the need for this data.” The EPA agrees that based on current trends in O<sub>3</sub> concentrations and the EPA’s own projections, states in Marginal nonattainment areas likely will comply with the revised NAAQS without additional state-directed controls, and as such, an EMP is not necessary in Marginal O<sub>3</sub> attainment areas. Accordingly, the EPA is finalizing a requirement for EMPs in areas classified as Moderate or above O<sub>3</sub> nonattainment and, thereby, removing the applicability of the requirement for Marginal areas. We believe this final requirement will provide the desired flexibility to allow states to identify enhanced monitoring needs while focusing resources for EMPs in areas of greater need of enhanced monitoring data.

Commenters expressed concerns over the lack of detail on what an approvable EMP would entail. As proposed, the

<sup>224</sup> NO<sub>y</sub> includes NO, NO<sub>2</sub>, and other oxidized nitrogen compounds (NO<sub>x</sub>).

EMPs would be reviewed and approved by the EPA Regional Administrator as part of the annual monitoring plan review process. One commenter recommended that the “EPA detail the requirements of the EMPs for ozone nonattainment areas in future implementation guidance.” One commenter stated that the “EPA should provide some coordination between regional offices and technical guidance to state agencies that would be of assistance in developing and executing the EMPs.” The requirements for the EMPs were intentionally left quite general in order to maximize the flexibility for states in identifying their specific data needs. Regional approval of the plans is required to ensure the enhanced monitoring planned will be commensurate with grant funds provided for EMPs. Nonetheless, the EPA understands the need for guidance on developing EMPs and commits to working with monitoring agencies and the regions to develop appropriate guidance on developing and reviewing EMPs.

## 2. Speciated VOC Measurements

Measurement of speciated VOCs important to O<sub>3</sub> formation is a key aspect of the PAMS program. The existing PAMS requirements allow for a number of options in measuring speciated VOCs at PAMS sites which include (1) hourly measurements using an automatic gas chromatograph (“autoGC”), (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 current options provided for VOC measurement limit the comparative value of the data being collected, and proposed that required PAMS sites must measure and report hourly speciated VOCs, which effectively would require them to use an autoGC to measure VOCs in lieu of canisters. 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. In addition, creating consistent monitoring requirements across the network would 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 VOC concentrations were relatively new and may not have been suitable for broad network use. At that time, GCs 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 autoGCs were universally appropriate due to the technical skill and effort necessary at that time to properly operate an autoGC.

While the basic principles of autoGC technology have not changed, the hardware and software of modern autoGCs are greatly improved over that available at the time of the original PAMS requirements. Based on advice from the CASAC AMMS, the EPA initiated an evaluation of current autoGCs potentially suitable for use in the PAMS network. Based on the preliminary results, the EPA believes that typical site operators, with appropriate training, will have the skill necessary to operate a modern autoGC successfully. Considering the advances in autoGC technology, the added value obtained from hourly data, and the proposed move of PAMS measurements to NCore sites in O<sub>3</sub> nonattainment areas, the EPA proposed to require hourly speciated VOC sampling at all PAMS sites. The EPA noted that this proposed requirement would effectively prevent the use of canisters to collect speciated VOCs at the required PAMS sites but that canister sampling may continue to be an appropriate method for collecting speciated VOCs at other locations as part of discretionary monitoring designed within the EMPs.

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 autoGCs may have for monitoring agencies, especially those that have experience with and have established effective and reliable

canister sampling programs. Therefore, the EPA requested 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.

The EPA received a number of comments on the requirement to measure hourly VOCs at required PAMS sites. Many commenters agreed with requiring hourly VOC data. One commenter agreed that “hourly VOC data collection is the most appropriate and useful for PAMS monitors” and that “it is only appropriate to approve an alternative data collection interval if it is believed that the high ozone in an area is due to other pollutants, such as NO<sub>x</sub> or methane.” One commenter stated they “supported the movement towards hourly PAMS VOC speciated measurements with flexibility to use canisters if programmatic or logistical needs indicate.”

However, some commenters raised concerns with the hourly VOC requirement. Some commenters questioned if autoGCs would be capable of measuring important VOC species in their environment. One commenter noted that in their location (high desert) “the largest VOC present in our inventory is creosote, a compound not commonly measured with this instrumentation.” One commenter stated that the “Southeastern United States is dominated by biogenic VOC emissions” and questioned “the benefits of an autoGC in understanding ozone formation in any potential nonattainment area in our State.”<sup>225</sup> Some questioned the detection capabilities of autoGCs as compared to canister sampling. One commenter found that the method detection limit (MDL) for their canister sampling was “consistently equal to or less than the autoGC instrumentation” based on the EPA’s autoGC evaluation laboratory report (RTI, 2014). Another commenter noted that the MDLs for many of the compounds and systems reported in the laboratory report were too high to be useful at PAMS sites. Another commenter stated that they found that “retention-time shifts made it difficult for instant identification of chemical peaks” and that “states should be allowed the flexibility to continue using canisters instead of autoGC.”

As noted in the preamble, and the comments received, the EPA is currently completing an evaluation of

<sup>225</sup> The EPA notes that isoprene (the dominant biogenic compound in the Southeast) is well measured using autoGCs. The EPA is also evaluating the potential of modern autoGC’s to measure alpha and beta pinene; however that work is not complete.



commercially available autoGCs. A copy of the report for the laboratory phase of the study is available in the docket (RTI, 2014). As noted in the laboratory report, the MDL estimates made for the laboratory study were not conducted according to normal MDL testing procedures and as such the results should only be used to compare the various instruments being tested against each other.<sup>226</sup> As part of the evaluation, the EPA identified the manufacturer's specifications for MDL. Most of the systems that are being evaluated have a manufacturer's estimated MDL in the range of 0.1 ppb to 0.5 ppb. Based on the evaluation of MDL capabilities and typical ambient concentrations of O<sub>3</sub> precursors, the EPA believes that autoGCs are an appropriate method for gathering VOC data at most urban locations. However, canister sampling may be more appropriate in locations with low VOC concentrations.

For the reasons discussed above and in the proposed rule, the EPA is finalizing a requirement for hourly speciated VOC measurements at required PAMS sites. The EPA believes that hourly VOC measurements will provide a more complete and consistent speciated VOC database to help meet the PAMS program objectives described above. Hourly VOC data are particularly useful in evaluating air quality models and performing diagnostic emission attribution studies. Longer time-averaged data are of lower value for model evaluation. Consistent monitoring requirements across the network will provide better data for analyzing regional trends and spatial patterns.

However, the EPA agrees that there may be locations where an autoGC may not be the most appropriate method for VOC measurement and that it is appropriate to allow for canister sampling in limited situations. Accordingly, the EPA is adding a waiver option (to be approved by the EPA Regional Administrator) to allow three 8-hour average samples every 3rd day as an alternative in cases where VOCs are not well measured by autoGC due to low concentrations of target compounds

<sup>226</sup> Several factors combined to result in the high relative MDL estimates reported in laboratory report. The MDL testing in the laboratory was conducted during concurrent tests for interferences from humidity and temperature. In addition, the MDL testing was conducted at relatively high concentrations compared to the concentrations testing would be conducted at for conventional MDL testing. Finally, as noted in the laboratory report, a number of instruments were having technical difficulties during the testing which greatly impacted their MDL results. The EPA is continuing the autoGC evaluation and has conducted a field study during the summer of 2015. A final report is expected in early 2016.

or where the predominant VOC compounds cannot be measured using autoGC technology (e.g., creosote in high desert environments). This alternative sampling frequency was selected to be consistent with the sampling frequency selected for carbonyls, which is discussed later in this preamble.

### 3. Carbonyl Measurements

Carbonyls include a number of compounds important to O<sub>3</sub> formation that cannot currently be measured using the autoGCs or canisters used at PAMS sites to measure speciated VOCs. 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 are currently required to be measured in the PAMS program—formaldehyde, acetaldehyde, and acetone.

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<sub>3</sub> under the 8-hour O<sub>3</sub> 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<sub>3</sub>) 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<sub>3</sub> formation determined that carbonyls, especially formaldehyde, are very important to O<sub>3</sub> formation (Cavender, 2013). CASAC AMMS (U.S. EPA, 2011f) 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<sub>3</sub> chemistry almost everywhere." Although the EPA recognizes the issues that have been raised about the current method of measuring carbonyls, due to the importance of carbonyls to understanding O<sub>3</sub> chemistry, the EPA proposed to require all required PAMS sites to measure carbonyls.

Several commenters agreed with the need for carbonyl data at PAMS sites. However, a number of commenters questioned the proposed frequency of eight 3-hour samples every day during the PAMS sampling season (June through August). Several commenters indicated that the frequency was too high. One commenter noted that the requirement would require 800 samples per season at each PAMS site and pointed out that this requirement, which was required at the inception of the PAMS program in the 1990s was "found to be prohibitively expensive, technically unsustainable, and qualitatively compromised." Another commenter stated that "this level of sampling would require a substantial amount of agency resources and seems unduly burdensome." A number of commenters also questioned the commercial availability of an 8-channel carbonyl sampler that would be needed to take eight 3-hour samples daily. In light of the comments and upon further review, the EPA agrees that the proposed frequency is unduly burdensome and is finalizing a requirement with a lower frequency.

A number of alternative frequencies were suggested in the comments. Several commenters suggested a frequency of three 8-hour samples on either a 1-in-6 day or 1-in-3 day basis. Another commenter suggested a frequency of eight 3-hour samples on a 1 in 6 day basis. The EPA notes that sampling on a 1-in-6 day frequency would lead to as little as 15 sampling days per PAMS sampling season. The EPA believes that 15 sampling days is too few to provide a meaningful representation of carbonyl concentrations over the PAMS sampling period. A sampling frequency of 1-in-3 days would lead to 30 sampling days per season with each day of the week being represented at least 4 times per sampling season. With regards to samples per day, a 3-hour sampling duration provides a better diurnal representation of carbonyl sampling compared with an 8-hour sampling duration; however 8-hour sampling can provide information useful for evaluating diurnal differences in carbonyl concentrations. Upon further consideration and in light of the comments received, the EPA is finalizing a carbonyl sampling requirement with a frequency of three 8-hour samples on a 1-in-3 day basis. This final requirement will result in approximately 90 samples per PAMS sampling season which the EPA believes is not unduly burdensome and

will provide a reasonable representation of carbonyl concentrations.

A number of commenters noted the ongoing development of continuous formaldehyde instruments, and recommended that EPA allow for continuous formaldehyde measurements as an alternative to the manual cartridge based TO-11A method. The EPA agrees that continuous formaldehyde, with the ability to obtain hourly averaged measurements, would be a significantly more valuable than the longer averaged measurements. As a result, the EPA has added an option to allow for continuous formaldehyde as an alternative to the carbonyl measurements using TO-11A.

#### 4. Nitrogen Oxides Measurements

It is well known that NO and NO<sub>2</sub> play important roles in O<sub>3</sub> formation (U.S. EPA, 2013, Section 3.2.2). Under the current network design, Type 2 PAMS sites are required to measure NO<sub>x</sub> (which by definition is the sum of NO and NO<sub>2</sub>), and Types 1, 3, and 4 sites are required to measure NO<sub>y</sub>. NCore sites are currently required to measure NO<sub>y</sub> but are not required to measure NO<sub>2</sub> separately.

In conventional NO<sub>x</sub> analyzers, NO<sub>2</sub> is determined as the difference between the measured NO and NO<sub>x</sub> concentrations. However, due to the non-selective reduction of oxidized nitrogen compounds by the molybdenum converter used in conventional NO<sub>x</sub> monitors, the NO<sub>2</sub> measurement made by conventional NO<sub>x</sub> monitors can be biased high due to the varying presence of NO<sub>z</sub> compounds that may be reported as NO<sub>2</sub>. The unknown bias from the NO<sub>z</sub> compounds is undesirable when attempting to understand O<sub>3</sub> chemistry.

Improvements in reactive nitrogen measurements have been made since the original PAMS requirements were promulgated that allow for improved NO<sub>2</sub> measurements. Selective photolytic converters have been developed that are not significantly biased by NO<sub>z</sub> compounds (Ryerson et al., 2000). Monitors using photolytic converters are commercially available and have been approved as FEMs for the measurement of NO<sub>2</sub>. In addition, methods that directly read NO<sub>2</sub> have been developed that allow for very accurate readings of NO<sub>2</sub> without some of the issues inherent to the "difference method" used in converter-based NO<sub>x</sub> analyzers. However, these direct reading NO<sub>2</sub> analyzers generally do not provide an NO estimate, and would need to be paired with a converter-based NO<sub>x</sub> monitor or NO<sub>y</sub> monitor in order to also measure NO.

As discussed above, the EPA is finalizing a PAMS network design such that PAMS measurements will be required at existing NCore sites in CBSAs with a population of 1,000,000 people or more. NCore sites currently are required to measure NO and NO<sub>y</sub>. NCore sites are not currently required to measure NO<sub>2</sub>. Due to the importance of accurate NO<sub>2</sub> data to the understanding of O<sub>3</sub> formation, the EPA proposed to require NO<sub>2</sub> measurements at required PAMS sites. Since existing NCore sites currently measure NO<sub>y</sub>, either a direct reading NO<sub>2</sub> analyzer or a photolytic-converter NO<sub>x</sub> analyzer could be used to meet the proposed requirement. The EPA believes conventional NO<sub>x</sub> analyzers would not be appropriate for making PAMS measurements due to the uncertainty caused by interferences from NO<sub>z</sub> compounds.

A number of commenters questioned the need for both NO<sub>y</sub> and NO<sub>2</sub> measurements at PAMS sites. One commenter stated that "in dense urban areas an NO/NO<sub>2</sub>/NO<sub>x</sub> instrument may be adequate but in a more rural area an NO/NO<sub>y</sub> instrument may be preferable." Another commenter stated that due to the size of the grid cells used in grid models that "the impact of NO<sub>z</sub> interferences would be very small compared to other modeling uncertainties such as emission inventories and mixing heights." Another commenter suggested that "EPA should provide clear and specific guidance on how agencies can request that the NO<sub>y</sub> monitoring be eliminated from the NCore suite based on comparative data between the NO<sub>2</sub> and NO<sub>y</sub> monitors."

The comments suggest that the model's ability to simulate the partitioning of reactive nitrogen is unimportant because there may be other errors in the model. The EPA believes that measurements should be routinely collected so that it can be demonstrated that the chemistry, meteorology, and emissions in the model are all of sufficient reliability for use in informing air quality management decisions. Monitoring sites rarely fall into simple categories of urban or rural, and the speciation of NO<sub>y</sub> varies considerably as a function of meteorology and time of day at a given site. The state-of-the-science in regulatory air quality modeling is such that accurate measurements of key O<sub>3</sub> precursors must be available to demonstrate the credibility of the model predictions. The increased availability of special field study observations is leading to increased scrutiny of the chemical mechanisms used in regulatory modeling. Comprehensive and accurate

measurement sites are needed to demonstrate the adequacy of the models and to respond to these challenges.

Measurements of NO, NO<sub>2</sub>, and NO<sub>y</sub> concentrations are critical to understanding atmospheric aging and photochemistry. These measurements will provide essential information about whether NO<sub>y</sub> compounds are fresh or aged which is important for understanding both local photochemistry (*i.e.* through indicator ratios to distinguish NO<sub>x</sub> vs VOC limited conditions) as well as for characterizing transport from upwind regions. These evaluations may be conducted using observations, box modeling or through complex photochemical grid based modeling. Accurate speciated and total NO<sub>y</sub> measurements are necessary for all three types of analysis. For these reasons, the EPA is finalizing the requirement for required PAMS sites to measure true NO<sub>2</sub> in addition to NO and NO<sub>y</sub>.

#### 5. Meteorology Measurements

The current PAMS requirements require monitoring agencies to collect surface meteorology at all required PAMS sites. As noted in the EPA's Technical Assistance Document (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 understanding O<sub>3</sub> formation, the EPA proposed to specify that required PAMS sites are required to collect wind direction, wind speed, temperature, humidity, atmospheric pressure, precipitation, solar radiation, and UV radiation. Since NCore sites are currently required to measure several of these surface meteorological parameters, the net impact of the proposal was to add the requirement for the monitoring of atmospheric pressure, precipitation, solar radiation, and UV radiation at affected NCore sites. The EPA received no significant comments on this portion of the proposal, and therefore is finalizing the requirement as proposed.

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 direction 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<sub>3</sub> 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 required PAMS sites would be prohibitive. Therefore, the EPA did not propose to add upper air wind speed and direction as required meteorological parameters to be monitored at required 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 EMP.

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 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<sub>3</sub> modeling, the EPA proposed to add the requirement for monitoring agencies to measure mixing height at required PAMS sites.

A number of commenters questioned the need for mixing height measurements at PAMS sites. One commenter stated, "the photochemical modeling community has a long history of relying upon National Weather Service measurements for mixing height." Another commenter stated that

"in some areas of the country the models used to predict mixing height are adequate, but in other mountainous or marine areas model-predicted mixing height data is inadequate." Accurate estimates of mixing height are important for appropriately characterizing concentrations of O<sub>3</sub> and O<sub>3</sub> precursors. Mixing height is also important for characterizing how modeled O<sub>3</sub> may change as a result of changing NO<sub>x</sub> and VOC concentrations. For instance, if the modeled mixing height is too low causing unrealistically high concentration of NO<sub>x</sub>, then O<sub>3</sub> destruction could be predicted when O<sub>3</sub> production may be happening in the atmosphere. When this or the opposite situation exists in modeling it may lead O<sub>3</sub> response to emissions changes that are less reliable for air quality planning purposes. While models are believed to do a reasonable job of predicting mixing height during the day, there is considerably more uncertainty in predicting this parameter during morning and evening transition periods and at night. Model O<sub>3</sub> predictions are particularly sensitive to mixing height during the time periods for which uncertainty in this parameter is greatest.

Several commenters noted that nearby National Oceanic and Atmospheric Administration (NOAA) Automated Surface Observing System (ASOS) sites may be a better alternative for collection of mixing height data. As indicated in the proposal, the EPA is aware of the network of ceilometers operated by NOAA as part of 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 and NOAA has no current plans to measure continuous mixing height in the future. 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 included 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 when such data are suitable and available.

The EPA is finalizing the requirement for the measurement of mixing height at required PAMS sites due to the importance of mixing height in O<sub>3</sub> modeling. A waiver option, to be approved by the Regional Administrator, is also being included to allow mixing height measurements to be obtained from other nearby sites (e.g., NOAA ASOS 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<sub>3</sub> formation. However, the EPA notes that in many areas the highest O<sub>3</sub> concentrations are observed outside of the PAMS season. As an example, the highest O<sub>3</sub> 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<sub>3</sub> episodes.

The CASAC AMMS (U.S. EPA, 2011f) 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." 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<sub>3</sub> 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 proposed 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<sub>3</sub> may be expected. No significant comments were received on the proposed PAMS season, and as such, for the reasons stated here and in the proposal, the EPA is not changing the 3-month PAMS season of June, July, and August.

The EPA believes that the 3-month PAMS season will provide a consistent data set of O<sub>3</sub> and O<sub>3</sub> precursor measurements for addressing the national PAMS objectives. Monitoring agencies are strongly encouraged to consider collecting PAMS measurements in additional periods beyond the required PAMS season as part of their EMP. The monitoring agencies should consider factors such as the periods of expected peak O<sub>3</sub> concentrations and regional consistency when determining potential expansion of their specific monitoring periods beyond the required PAMS season.

#### 7. Timing and Other Implementation Issues

The EPA recognizes that the changes to the PAMS requirements will require resources and a reasonable timeline in order to be successfully implemented. The PAMS program is funded, in part, as part of the EPA's section 105 grants. The EPA believes that the current national funding level of the PAMS program is sufficient to support these final changes, but changes in the distribution of PAMS funds will need to be made. The network design changes will require some monitoring agencies to start collection of new PAMS measurements, while other monitoring agencies will see reductions in PAMS measurement requirements. The EPA will work with the NAACA, AAPCA, and other monitoring agencies to develop an appropriate PAMS grant distribution strategy.

In addition to resources, the affected monitoring agencies will need time to implement the revised PAMS requirements. For the required PAMS sites, monitoring agencies can determine now which NCore sites will be required to make PAMS measurements based on readily available census data. However, monitoring agencies will still need time to evaluate and seek approval for alternative sites or alternative VOC methods. In addition, monitoring agencies will need time to make capital investments (primarily for the installation of autoGCs, NO<sub>2</sub> monitors, and ceilometers), prepare appropriate QA documents, and develop the expertise needed to successfully collect PAMS measurements via training or otherwise. In order to ensure monitoring agencies have adequate time to plan and successfully implement the revised PAMS requirements, the EPA is requiring that monitoring agencies identify their plans to implement the PAMS measurements at NCore sites in their Annual Network Plan due July 1, 2018, and to begin making PAMS

measurements at NCore sites by June 1, 2019. The EPA believes some monitoring agencies may be able to begin making PAMS measurements sooner than June 2019 and encourages early deployment where possible.

Monitoring agencies will need to wait until O<sub>3</sub> designations are made to officially determine the applicability of the EMP requirement. The EPA proposed to allow two years after designations to develop EMPs, and that the EMPs would be submitted as part of their Annual Network Plan. Several commenters stated that due to the level of planning and coordination required for the EMPs, that the plans should instead be included as part of the 5-year network assessment. While the EPA agrees that the EMPs will require a substantial amount of planning and coordination, the next 5 year network assessment will not be due until July 1, 2020—nearly 5 years from the date of this final rulemaking. The EPA believes that it would be inappropriate to wait 5-years from the date of this rulemaking to develop plans for enhanced O<sub>3</sub> monitoring. In addition, the EPA believes that the first round of EMP development should receive additional focus and review that may not be afforded as part of the larger network assessment. Finally, most monitoring agencies will be aware of their likely O<sub>3</sub> attainment status well in advance of the official designations. In order to ensure timely development of the initial EMPs, the EPA is requiring affected monitoring agencies to submit their initial EMPs no later than two years following designations. States in the OTR do not need to wait until designations to determine EMP applicability and may not be classified as Moderate or above. As such, the final rule includes a requirement for states in the OTR to submit their initial EMPs by October 1, 2019 (which is consistent with the expected timeline for the remaining EMPs). However, subsequent review and revisions to the EMPs are to be made as part of the 5-year network assessments beginning with the assessments due in 2025.

#### D. Addition of a New FRM for O<sub>3</sub>

The use of FRM analyzers for the collection of air monitoring data provides uniform, reproducible measurements of concentrations of criteria pollutants in ambient air. FRMs for various pollutants are described in several appendixes to 40 CFR part 50. For most gaseous criteria pollutants (including O<sub>3</sub> in Appendix D of part 50), the FRM is described as a particular measurement principle and calibration procedure to be implemented, with

further reference to specific analyzer performance requirements specified in 40 CFR part 53.

The EPA allows new or alternative monitoring technologies—identified as FEMs—to be used in lieu of FRMs, provided that such alternative methods produce measurements closely comparable to corresponding FRM measurements. Part 53 sets forth the specific performance requirements as well as the performance test procedures required by the EPA for determining and designating both FRM and FEM analyzers by brand and model.

To be used in a determination of compliance with the O<sub>3</sub> NAAQS, ambient O<sub>3</sub> monitoring data must be obtained using either a FRM or a FEM, as defined in parts 50 and 53. For O<sub>3</sub>, nearly all the monitoring methods currently used by state and local monitoring agencies are FEM (not FRM) continuous analyzers that utilize an alternative measurement principle based on quantitative measurement of the absorption of UV light by O<sub>3</sub>. This type of O<sub>3</sub> analyzer was introduced into monitoring networks in the 1980s and has since become the predominant type of method used because of its all-optoelectronic design and its ease of installation and operation.

The existing O<sub>3</sub> FRM specifies a measurement principle based on quantitative measurement of chemiluminescence from the reaction of ambient O<sub>3</sub> with ethylene (ET-CL). Ozone analyzers based on this FRM principle were once widely deployed in monitoring networks, but now they are no longer used for routine O<sub>3</sub> field monitoring because readily available UV-type FEMs are substantially less difficult to install and operate. In fact, the extent of the utilization of UV-type FEMs over FRMs for O<sub>3</sub> monitoring is such that FRM analyzers have now become commercially unavailable. The last new commercial FRM analyzer was designated by the EPA in 1979. The current list of all approved FRMs and FEMs capable of providing ambient O<sub>3</sub> 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, 2014e). However, that list does not indicate whether or not each listed method is still commercially available.

#### 1. Proposed Changes to the FRM for O<sub>3</sub>

Although the existing O<sub>3</sub> FRM is still a technically sound methodology, the lack of commercially available FRM O<sub>3</sub> analyzers severely impeded the use of FRM analyzers, which are needed for quality control purposes and as the standard to which candidate FEMs are

required to be compared. Therefore, the EPA proposed to establish a new FRM measurement technique for O<sub>3</sub> based on NO-chemiluminescence (NO-CL) methodology. This new chemiluminescence technique is very similar to the existing ET-CL methodology with respect to operating principle, so the EPA proposed to incorporate it into the existing O<sub>3</sub> FRM as a variation of the existing ET-CL methodology, coupled with the same existing FRM calibration procedure.

A revised Appendix D to 40 CFR part 50 was proposed to include both the original ET-CL methodology as well as the new NO-CL methodology, such that use of either measurement technique would be acceptable for implementation in commercial FRM analyzers. Currently, two O<sub>3</sub> analyzer models (from the same manufacturer) employing the NO-CL methodology have been designated by the EPA as FEMs and would qualify for re-designation as FRMs under the revised O<sub>3</sub> FRM. The rationale for selecting the new NO-CL FRM methodology, including what other methodologies were also considered, and additional information to support its selection are discussed in the preamble to the proposal for this action (79 FR 75366-75368). No substantive change was proposed to the existing O<sub>3</sub> FRM calibration procedure, which would be applicable to both chemiluminescence FRM methodologies.

The proposed FRM in part 50, Appendix D also included numerous editorial changes to provide clarification of some provisions, some revised wording, additional details, and a more refined numbering system and format consistent with that of two other recently revised FRMs (for SO<sub>2</sub> and CO).

As noted in the proposal, there is substantial similarity between the new and previously existing FRM measurement techniques, and comparative field data show excellent agreement between ambient O<sub>3</sub> measurements made with the two techniques (U.S. EPA 2014f). Therefore, the EPA believes that there will be no significant impact on the comparability between existing ambient O<sub>3</sub> monitoring data based on the original ET-CL methodology and new monitoring data that may be based on the NO-CL methodology.

The proposed FRM retains the original ET-CL methodology, so all existing FEMs, which were designated under part 53 based on demonstrated comparability to that ET-CL methodology, will retain their FEM designations. Thus, there will be no negative consequences or disruption to

monitoring agencies, which will not be required to make any changes to their O<sub>3</sub> monitors due to the revised O<sub>3</sub> FRM. New FEMs would be designated under part 53, based on demonstrated acceptable comparability to either FRM methodology.

## 2. Comments on the FRM for O<sub>3</sub>

Comments that were received from the public on the proposed new O<sub>3</sub> FRM technique are addressed in this section. Most commenters expressed general support for the proposed changes, although a few commenters expressed some concerns. The most significant issue discussed in comments was the relatively small but nevertheless potentially significant interference of water vapor observed in the ET-CL technique. As some comments pointed out, this interference is positive and could possibly affect NAAQS attainment decisions. The available NO-CL FEM analyzers include a sample dryer, which minimizes this interference. As noted previously, very few, if any, ET-CL FRM analyzers are still in operation. The ET-CL (with and without a sample dryer), the proposed NO-CL FRM, and all designated FEM analyzers have demonstrated compliance with the substantially reduced water vapor interference equivalent limit specified in 40 CFR part 53.

The proposed FRM mentioned the need for a sample air dryer for both ET-CL and NO-CL FRM analyzers. In response to these comments, the wording of the ET-CL FRM has been augmented to clarify the requirement for a dryer in all newly designated FRMs (the only change being made by the EPA to the existing ET-CL FRM as proposed). Also, the interference equivalent limit for water vapor in part 53 was proposed to be substantially reduced from the current 0.02 ppm to 0.002 ppm. The interference equivalent test for water vapor applicable to the new NO-CL candidate FRM analyzers (specified in Table B-3 of part 53) was proposed to be more stringent than the corresponding existing test for ET-CL FRM analyzers by requiring that water vapor be mixed with O<sub>3</sub>. This mixing requirement was not part of the existing test for ET-CL candidate analyzers (denoted by footnote 3 in Table B-3). However, in further response to these commenters' concerns, the EPA has modified Table B-3 to extend this water vapor mixing requirement to newly designated ET-CL analyzers, as well. These measures should insure that potential water vapor interference is minimized in all newly designated FRM analyzers.

Several comments indicated concern that currently-designated FEM analyzers retain their designation without retesting if the new FRM were promulgated. The current ET-CL FRM is being retained; therefore, it is not necessary to make these new requirements retroactive to existing designated FEM analyzers. The existing FEM analyzers will not be required to be retested, and their FEM designation will be retained so that there will be no disruption to current monitoring networks.

Although beyond the scope of this rulemaking, other comments concerned potential hazards of the NO compressed gas supply required for NO-CL analyzer operation, and the current non-availability of a photolytic converter to provide an alternative source of NO from a less hazardous nitrous oxide gas supply. With regard to the photolytic converter, the EPA would approve such a converter as a source of NO if requested by an FRM analyzer manufacturer, upon demonstration of adequate functionality.

A few commenters liked the "scrubberless UV absorption" (SL-UV) measurement technique. The EPA has identified the SL-UV method as a potentially advantageous candidate for the O<sub>3</sub> FRM, but could not propose adopting it until additional test and performance information becomes available. A related comment requested clarification that promulgation of the proposed revised FRM would not preclude future consideration of other O<sub>3</sub> measurement techniques such as SL-UV. In response, the EPA can always consider new technologies for FRMs under 40 CFR 53.16 (Supersession of reference methods). However, a revised or amended FRM that included the SL-UV technique, as set forth in Appendix D of 40 CFR part 50, would have to be promulgated as part of a future rulemaking, before a SL-UV analyzer could be approved as an FRM under 40 CFR part 53.

One comment suggested that the value for the absorption cross section of O<sub>3</sub> at 254 nm used by the FRM's calibration procedure should be changed. The comment indicated that the nearly 2% difference effectively lowers the O<sub>3</sub> NAAQS by that amount. Using the corrected value would resolve much of the difference observed between O<sub>3</sub> measurements calibrated against the UV standard reference photometer versus those calibrated using NO gas phase titration and it would allow the EPA to adopt the less complex and more economical Gas Phase Titration (GPT) technique as the primary calibration standard for the

FRM. The EPA will await the results of further studies determining the value of the O<sub>3</sub> cross section at 254 nm before making a change to the calibration procedures and will not finalize changes to the calibration procedures in this final rule.

#### *E. Revisions to the Analyzer Performance Requirements*

##### 1. Proposed Changes to the Analyzer Performance Requirements

In close association with the proposed O<sub>3</sub> FRM, the EPA also proposed changes to the associated analyzer performance requirements for designation of FRMs and FEMs for O<sub>3</sub>, as set forth in 40 CFR part 53. These changes were largely confined to Table B-1, which specifies performance requirements for FRM and FEM analyzers for SO<sub>2</sub>, CO, O<sub>3</sub>, and NO<sub>2</sub>, and to Table B-3, which specifies test concentrations for the various interfering agent (interferent) tests. Minor changes were also proposed for Figure B-5 and the general provisions in subpart A of part 53. All of these proposed changes are described and discussed more fully in the preamble to the proposal for this action (79 FR 75368-75369).

Modest changes proposed for Table B-3 would add new interferent test concentrations specifically for NO-CL O<sub>3</sub> analyzers, which include a test for NO<sub>2</sub> interference.

Several changes to Table B-1 were proposed. Updated performance requirements for "standard range" analyzers were proposed to be more consistent with current O<sub>3</sub> analyzer performance capabilities, including reduced limits for noise allowance, lower detectable limit (LDL), interference equivalent, zero drift, span drift, and lag, rise, and fall times. The previous limit on the total of all interferents was proposed to be withdrawn as unnecessary and to be consistent with that same change made previously for SO<sub>2</sub> and CO analyzers. Also, the span drift limit at 20% of the upper range limit (URL) was proposed to be withdrawn because it has similarly been shown to be unnecessary and to maintain consistency with that same change made previously for SO<sub>2</sub> and CO analyzers.

The form of the precision limits at both 20% and 80% of the URL was proposed to be changed from ppm to percent. The proposed new limits (in percent) were set to be equivalent to the previously existing limits (in ppm) and thus remain effectively unchanged. This change in form of the precision limits in Table B-1 has been previously made for SO<sub>2</sub> and CO analyzers, and was

proposed to extend also to analyzers for NO<sub>2</sub>, (again with equivalent limits) for consistency and to simplify Table B-1 across all types of analyzers to which the table applies. A new footnote proposed for Table B-1 clarifies the new form for precision limits as "standard deviation expressed as percent of the URL." Also proposed was a revision to Figure B-5 (Calculation of Zero Drift, Span Drift, and Precision) to reflect the changes proposed in the form of the precision limits and the withdrawal of the limits for total interference equivalent.

Concurrent with the proposed changes to the performance requirements for candidate O<sub>3</sub> analyzers, the EPA conducted a review of all designated FRM and FEM O<sub>3</sub> analyzers currently in production or being used, and verified that all meet the proposed new performance requirements. Therefore, none would require withdrawal or cancellation of their current FRM or FEM respective designations.

Finally, the EPA proposed new, optional, "lower range" performance limits for O<sub>3</sub> analyzers operating on measurement ranges lower (*i.e.*, more sensitive) than the standard range specified in Table B-1. The new performance requirements are listed in a new "lower range" column in Table B-1 and will provide for more stringent performance in applications where more sensitive O<sub>3</sub> measurements are needed.

Two minor changes were proposed to the general, administrative provisions in Subpart A of part 53. These include an increase in the time allowed for the EPA to process requests for approval of modifications to previously designated FRMs and FEMs in 53.14 and the withdrawal of a requirement for annual submission of Product Manufacturing Checklists associated with FRMs and FEMs for PM<sub>2.5</sub> and PM<sub>10-2.5</sub> in 53.9. No comments were received on these proposed changes and the EPA will be finalizing these revisions in this rulemaking.

##### 2. Comments on the Analyzer Performance Requirements

Several comments were received related to the proposed changes to the analyzer performance requirements of part 53, and most were supportive. Comments from a few monitoring agencies suggested that the more stringent performance requirements proposed might be difficult to achieve or would increase monitor maintenance and cost. The EPA is also clarifying that these requirements apply only to the performance qualification requirements for designations of new FRM and FEM

analyzers and will have no impact on a monitoring agency's operation of existing O<sub>3</sub> analyzers.

More specific comments from an analyzer manufacturer pointed out that the proposed lower limits for noise and LDL may be too stringent, the former because low-cost portable analyzers may have shorter absorption cells, and the latter because of limitations of current calibration technology. After further consideration of available analyzer performance data in light of these comments, the EPA agrees and is changing the noise limits from the proposed values of 1 ppb and 0.5 ppb (for the standard and lower ranges, respectively) to 2.5 ppb and 1 ppb (respectively). The EPA is also changing the LDL limit from the proposed values of 3 ppb and 1 ppb (respectively) to 5 ppb and 2 ppb (respectively). These new limits are still considerably more stringent than the previous limits (for the standard range) and are also consistent with those recommended by the commenter and the current performance capabilities of existing analyzer/calibration technology.

This commenter also pointed out that the proposed lower limit for 12-hour zero drift, together with the way the prescribed test is carried out, resulted in the test being dominated by analyzer noise rather than drift. The EPA agrees with this comment in general but believes that further study is needed before any specific changes can be proposed for the 12-hour zero drift test, particularly since any such changes would affect analyzers for other gaseous pollutants, as well.

Other comments suggested that there was no need for the proposed new, low-range performance requirements, because of cost and that available calibrators would be inadequate for calibration of such low ranges. The EPA disagrees with these comments and believes, as noted in the proposal preamble, that there is a definite need for low-level O<sub>3</sub> measurements in some applications and that suitable calibration for such low-level measurement ranges can be adequately carried out. As stated previously, the new "low range" specifications for O<sub>3</sub> analyzers are optional.

Several comments pointed out some typographical errors related to footnotes in Table B-3, as proposed; these errors have been corrected in the version of Table B-3 being finalized today.

EPA is finalizing the proposed amendments to both the O<sub>3</sub> FRM in Appendix D of part 50 and provisions in part 53, modified as described above, in response to the comments received.

## VII. Grandfathering Provision for Certain PSD Permits

This section addresses the grandfathering provision for certain Prevention of Significant Deterioration (PSD) permit applications that is being finalized in this rule. Section VIII.C of this preamble contains a description of the PSD and Nonattainment New Source Review (NNSR) permitting programs and additional discussion of the implementation of those programs for the O<sub>3</sub> NAAQS.

### A. Summary of the Proposed Grandfathering Provision

The EPA proposed to amend the PSD regulations to add a transition plan that would address the extent to which the revised O<sub>3</sub> NAAQS will apply to pending PSD permit applications. This transition plan is reflected in a grandfathering provision that applies to permit applications that meet certain milestones in the review process prior to either the signature date or effective date of the revised O<sub>3</sub> NAAQS. Absent such a grandfathering provision in the EPA's regulations, the EPA interprets section 165(a)(3)(B) of the CAA and the implementing PSD regulations at 40 CFR 52.21(k)(1) and 51.166(k)(1) to require that PSD permit applications include a demonstration that emissions from the proposed facility will not cause or contribute to a violation of any NAAQS that is in effect as of the date the PSD permit is issued. The proposal included a grandfathering provision that would enable eligible PSD applications to make the demonstration that the proposed project would not cause or contribute to a violation of any NAAQS with respect to the O<sub>3</sub> NAAQS in effect at the time the relevant permitting benchmark for grandfathering was reached, rather than the revised O<sub>3</sub> NAAQS. We proposed that the grandfathering provision would apply specifically to either of two categories of pending PSD permit applications: (1) Applications for which the reviewing authority has formally determined that the application is complete on or before the signature date of the final rule revising the O<sub>3</sub> NAAQS; and (2) applications for which the reviewing authority has first published a public notice of the draft permit or preliminary determination before the effective date of the revised NAAQS.

In the proposal, we also noted that for sources subject to the federal PSD program under 40 CFR 52.21, the EPA and air agencies that have been delegated authority to implement the federal PSD program for the EPA would apply the grandfathering provision to

any PSD application that satisfies either of the two criteria that make an application eligible for grandfathering. Accordingly, if a particular application does not qualify under the first criterion based on a complete application determination, it may qualify under the second criterion based on a public notice announcing the draft permit or preliminary determination. Conversely, a source may qualify for grandfathering under the first criterion, even if it does not satisfy the second.

The EPA also proposed revisions to the PSD regulations at 40 CFR 51.166 that would afford air agencies that issue PSD permits under a SIP-approved PSD permit program the discretion to adopt provisions into the SIP that allow for grandfathering of pending PSD permits under the same circumstances as set forth in the federal PSD regulations. With regard to implementing the grandfathering provision, we also explained that air agencies 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. In addition, the proposal recognized that some air agencies do not make formal completeness determinations; thus, only the latter criterion based on the issuance of a public notice would be relevant in such cases and the state could elect to adopt only that criterion into its SIP. Accordingly, the EPA proposed to add a grandfathering provision to 40 CFR 51.166 containing the same two criteria as proposed for 40 CFR 52.21.

### B. Comments and Responses

Many of the comments supported the concept of grandfathering. Some of these comments, mostly by state and local air agencies, supported the grandfathering provision as proposed. Many others recommended alternative approaches to grandfathering based on several different dates. Several comments recommended that air agencies be allowed to grandfather certain PSD permit applications and issue a PSD permit based on the 2008 O<sub>3</sub> NAAQS after the area is designated nonattainment for the revised O<sub>3</sub> NAAQS. An opposing set of comments, representing a coalition of eight environmental groups and one health advocacy group, strongly objected to the proposal for grandfathering, claiming that the EPA did not have any authority under the CAA to exempt or grandfather permit applicants from the statutory PSD permitting requirements. We are addressing some of these comments below and others in the Response to

Comment Document that is included in the docket for this rule.

Comments that recommended broadening the scope of the proposed grandfathering provision suggested a variety of approaches. Some air agency and industry comments recommended that the EPA adopt a grandfathering provision applicable only to those PSD applications for which the reviewing authority has determined the application to be complete on or before the signature date of the revised NAAQS. Other air agency and industry comments recommended that grandfathered status be determined only on the basis of whether the relevant permitting milestone has been achieved by the effective date of the revised NAAQS.

The EPA disagrees with these comments; the final rule uses separate dates for the two grandfathering milestones, as proposed. If the effective date of the revised NAAQS were used as the date for the complete application milestone, this could lead to pressure on state permitting authorities to prematurely issue completeness determinations in order to qualify for the grandfathering provision in the time period between signature of this final rule and the effective date. Using the signature date of the revised O<sub>3</sub> NAAQS as the date for the grandfathering milestone based on the completeness determination is thus intended to help preserve the integrity of the completeness determination process. Permit applications that have not yet been determined complete can be supplemented or revised to address the revised O<sub>3</sub> standards before the completeness determination is issued. Conversely, the amount and type of work required for a preliminary determination or a draft permit reduces the risk that such a document would be released prematurely merely to qualify for grandfathering. Similarly, because these documents are released for the purpose of providing an adequate opportunity for public participation in the permitting process, it would not behoove a reviewing authority to precipitately release such documents merely to satisfy the grandfathering milestone. Accordingly, the EPA does not have the same concerns about using the effective date of this final rule for the preliminary determination or draft permit milestone and further finds it reasonable to provide additional time for satisfying this milestone. Moreover, using the proposed milestones and corresponding dates is consistent with the milestones and corresponding dates that were used in the grandfathering provisions for the 2012 PM<sub>2.5</sub> NAAQS.



Several other comments recommended that the grandfathering provision apply to all PSD applications for which a final PSD permit will be issued prior to the effective date of the area designations for the revised NAAQS. Some of these comments explained that without some transition provisions in the final rule, it may be impossible for a source to demonstrate attainment if the current ambient air monitoring data indicates a revised, lowered standard is not being met. The comments also suggested that the extended period for grandfathering a source from the revised NAAQS would provide states with additional time to establish offset banks or similar systems for new nonattainment areas.

Other comments recommended that air agencies be allowed to grandfather either all or certain PSD permit applications received before the effective date of the final nonattainment designations for the revised O<sub>3</sub> NAAQS. These comments supported allowing air agencies to issue PSD permits to grandfathered sources even after the area in which the source proposes to locate is designated nonattainment for the revised O<sub>3</sub> NAAQS. One comment saw this as being necessary because the development of the regulatory framework that will support the revised NAAQS, such as development of a credit market or even a transition into NNSR permitting, does not instantaneously accompany the revised standard. Hence, the comment added that “[d]uring the Interim Period (the time between the revision of the NAAQS rule and development of the regulatory framework) the project may be unable to secure offsets and no offsets would be available for purchase.” Another comment explained that the extended period for grandfathering sources from the revised O<sub>3</sub> NAAQS was needed to “minimize disruption to complex projects that may have been under development since before the EPA published the proposed NAAQS revision.” This comment noted the “PSD projects commonly undergo years of engineering and other development resources before an air permit application can be prepared.”

The EPA does not agree with the comments recommending that the EPA use a date after the effective date of the revised O<sub>3</sub> NAAQS as the date by which the permit application must reach the relevant milestone to qualify for grandfathering. The EPA does not believe it is appropriate to unreasonably or unnecessarily delay implementation of these revised standards under the PSD program. As explained in more detail below, the purpose of the

grandfathering provision is to provide a reasonable transition mechanism for certain PSD applications and the EPA believes that the milestones proposed and finalized here strike the appropriate balance in providing for such a reasonable transition. Moreover, in some cases, some of these recommended approaches could enable a situation where a PSD permit would be issued to a source during a future period when the area is designated nonattainment for the revised O<sub>3</sub> NAAQS. As explained below, the EPA does not believe that this specific outcome is permissible under the CAA.

The EPA does not agree with the comments suggesting that the grandfathering provision should be expanded to apply to any PSD application received before the effective date of the final nonattainment designations for the revised O<sub>3</sub> NAAQS. Because the process for reviewing PSD permit applications and issuing a final PSD permit is time consuming, such an approach could allow issuance of PSD permits to grandfathered sources even after the area in which the source proposes to locate is designated nonattainment for the revised O<sub>3</sub> NAAQS. The EPA does not agree that grandfathering should be extended in a way that would allow a source located in an area designated as nonattainment for a pollutant at the time of permit issuance to obtain a PSD permit for that pollutant rather than a NNSR permit. The EPA does not interpret the CAA or its implementing regulations to allow such an outcome. The PSD requirements under CAA section 165 only apply in areas designated attainment or unclassifiable for the pollutant. *Alabama Power v. Costle*, 636 F.2d 323, 365–66, 368 (D.C. Cir. 1980). Accordingly, the PSD implementing regulations at 40 CFR 52.21(i)(2) contain an exemption that provides that the substantive PSD requirements shall not apply to a pollutant if the owner or operator demonstrates that the facility is located in an area designated nonattainment for that pollutant under CAA section 107 of the Act. *See also* 40 CFR 51.166(i)(2) (allowing for the same exemption in SIP-approved PSD permitting programs). In addition, under CAA section 172(c)(5) implementation plans must require that permits issued to new or modified stationary sources “anywhere in the nonattainment area” meet the requirements of CAA section 173, which contains the NNSR permit requirements. *See* 40 CFR part 51, Appendix S, IV.A (providing that, if a major new source or major modification that would locate in an area designated

as nonattainment for a pollutant for which the source or modification would be major, approval to construct may be granted only if the specific conditions for NNSR are met, including obtaining emission offsets and an emission limitation that specifies the lowest achievable emissions rate). Moreover, given the adverse air quality conditions that already exist in a nonattainment area and the congressional directive to reach attainment as expeditiously as practicable, construction of a major stationary source that significantly increases emissions in such an area should be expected to address all of the NNSR requirements, which are designed to ensure that a new or modified major stationary source will not interfere with reasonable progress toward attainment, even if this could cause delay to the permit applicant.

With respect to the comments that suggested the effective date of the NAAQS should be used as the date for both milestones, the EPA does not agree that such a change is necessary. The purpose of the grandfathering provision is to provide a reasonable transition mechanism in the following circumstances: first, the PSD application is one for which both the applicant and the reviewing authority have committed substantial resources; and, second, this situation is one where the need to satisfy the demonstration requirement under CAA section 165(a)(3) could impact the reviewing authority’s ability to meet the statutory deadline for issuing a permit within one year of the completeness determination. In situations where the reviewing authority has not yet issued a completeness determination as of the signature date of the revised O<sub>3</sub> NAAQS, both the permit applicant and the reviewing authority have sufficient notice of the revised standard so that it can be addressed before the completeness determination is issued and the one-year clock begins to run. The grandfathering provision issued in this rulemaking is crafted to draw a reasonable balance that accommodates the requirements under both CAA sections 165(a)(3) and 165(c). Any modification of the dates further than is necessary to accommodate these concerns could upset this balance.

With respect to the comments that suggested adopting a grandfathering provision applicable only to those PSD applications for which the reviewing authority has determined the application to be complete on or before the signature date of the revised NAAQS, the EPA is not making this change because we understand that not all reviewing authorities issue formal completeness determinations. Including

a grandfathering provision based on the publication of a public notice of the draft permit or preliminary determination provides a reasonable transition mechanism for PSD applications in situations where the reviewing authority does not issue formal completeness determinations, but the applicant and the reviewing authority have both committed substantial resources to the pending permit application at the time the revisions to the O<sub>3</sub> NAAQS are finalized.

An opposing set of comments—submitted by a consortium of eight environmental groups and one health advocacy group—challenged the proposed grandfathering provision on the basis that the EPA did not have the legal authority to grandfather sources from PSD requirements. These commenters argued that the plain language of CAA section 165 forecloses the EPA's proposed approach and raised several other legal considerations. The EPA disagrees with these comments, including the interpretations of the CAA that they offer. As summarized in the rationale for the final action below in section VII.C of this preamble, the EPA believes that the CAA provides it authority and discretion to establish a PSD grandfathering provision such as the one being adopted today through a rulemaking process. The EPA is providing a further, detailed analysis fully responding to this set of comments, as well as other comments related to the grandfathering provision, in the Response to Comment Document in the docket for this rule.

### C. Final Action and Rationale

After consideration and evaluation of all the public comments received on the grandfathering provision, the EPA is finalizing this provision as proposed, with minor revisions that enhance the clarity of the grandfathering provision, without changing its substantive effect. While these revisions lead to slight differences in wording for the grandfathering provision for the 2012 PM<sub>2.5</sub> NAAQS and the grandfathering provision finalized in this rulemaking, those differences are not intended to create a different meaning; rather, the grandfathering provision finalized in this rulemaking is intended to have the same substantive effect and meaning for the revised O<sub>3</sub> standards as the grandfathering provision for the 2012 PM<sub>2.5</sub> NAAQS had for the revised PM standards. Other than those clarifying revisions, this final rule includes the same rule language for the grandfathering provision as previously proposed for the PSD regulations at 40

CFR 52.21(i)(12) and 51.166(i)(11), respectively. The provision in the final rule reflects the same two milestones and corresponding dates as the proposed grandfathering provision. Thus, under the grandfathering provision as finalized, either of the following two categories of pending PSD permit applications would be eligible for grandfathering: (1) Applications for which the reviewing authority has formally determined that the application is complete on or before the signature date of the revised O<sub>3</sub> NAAQS, or (2) applications for which the reviewing authority has first published a notice of a draft permit or preliminary determination before the effective date of the revised O<sub>3</sub> NAAQS. The EPA believes that it continues to be appropriate to include the two proposed milestones for pending permit applications to be eligible for grandfathering. While a completeness determination is often the first event, some air agencies do not determine applications complete as part of their permit process.

Under 40 CFR 52.21, a permit application may qualify for grandfathering under either of the two sets of milestones and dates contained in the provision. Where the EPA is the reviewing authority, the EPA intends to apply the grandfathering provision to PSD applicants pursuant to PSD regulations at 40 CFR 52.21 primarily through the use of the completeness determination milestone because the EPA Regional Offices make a formal completeness determination for any PSD application that they receive and review. The EPA is including the second criterion in 40 CFR 52.21 so that pending applications can still qualify for grandfathering under the second criterion if any air agency that incorporates 40 CFR 52.21 into a SIP-approved program does not make formal completeness determinations as part of its permit review process.

The EPA is also amending the PSD regulations at 40 CFR 51.166 to enable states and other air agencies that issue PSD permits under SIP-approved PSD programs to adopt a comparable grandfathering provision. Nevertheless, such air agencies have discretion to not grandfather PSD applications or to apply grandfathering under their approved PSD programs in another manner as long as that program is at least as stringent as the provision being added to 40 CFR 51.166. Accordingly, an air agency may elect to rely on both sets of milestones and dates or it may grandfather on the sole basis of only one set. However, the EPA anticipates that once a decision is made concerning the

use of either set of milestones and dates, the air agency will apply grandfathering consistently to all pending PSD permit applications.

As explained in more detail in the proposal, absent a regulatory grandfathering provision, the EPA interprets section 165(a)(3)(B) of the CAA and the implementing PSD regulations at 40 CFR 52.21(k)(1) and 51.166(k)(1) to require that PSD permit applications include a demonstration that emissions from the proposed facility will not cause or contribute to a violation of any NAAQS that is in effect as of the date the PSD permit is issued. However, reading CAA section 165(a)(3)(B) in context with other provisions of the Act and the legislative history, the EPA interprets the Act to provide the EPA with authority to establish grandfathering provisions through regulation. The EPA has explained its interpretation of its authority to promulgate grandfathering provisions in previous rulemaking actions, most recently in the rule establishing the grandfathering provision for the 2012 PM<sub>2.5</sub> NAAQS (78 FR 3086, 3254–56, January 15, 2013), as well as in the proposal for this final action. The EPA is providing additional discussion of this authority in the Response to Comment Document contained in the docket for this final action.

To summarize briefly, the addition of this grandfathering provision is permissible under the discretion provided by the CAA for the EPA to craft a reasonable implementation regulation that balances competing objectives of the statutory PSD program found in CAA section 165. Specifically, section 165(a)(3) requires a permit applicant to demonstrate that its proposed project will not cause or contribute to a violation of any NAAQS, while section 165(c) requires that a PSD permit be granted or denied within one year after the permitting authority determines the application for such permit to be complete. Section 109(d)(1) of the CAA requires the EPA to review existing NAAQS and make appropriate revisions every five years. When these provisions are considered together, a statutory ambiguity arises concerning how the requirements under CAA section 165(a)(3)(B) should be applied to a limited set of pending PSD permit applications when the O<sub>3</sub> NAAQS is revised. The Act does not clearly address how the requirements of CAA section 165(a)(3)(B) should be met for PSD permit applications that are pending when the NAAQS are revised, particularly when the EPA also determines that complying with the

demonstration requirement for the revised NAAQS could hinder compliance with the requirement under section 165(c) to issue a permit within one year of the completeness determination for a certain subset of pending permits. The CAA also does not address how the requirements of CAA sections 165(a)(3) and 165(c) should be balanced in light of the statutory requirement to review the NAAQS every five years. As Congress has not spoken precisely to this issue, the EPA has the discretion to apply a permissible interpretation of the Act that balances the statutory requirements to make a decision on a permit application within one year and to ensure the new and modified sources will only be authorized to construct after showing they can meet the substantive permitting criteria. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843–44 (1984).

In addressing these gaps in the CAA and the tension that may arise in section 165 in these circumstances, the EPA also applies CAA section 301, where the Administrator is authorized “to prescribe such regulations as are necessary to carry out his functions under this chapter.” Sections 165(a)(3) and 165(c) of the CAA make clear that the interests behind CAA section 165 include both protection of air quality and timely decision-making on pending permit applications. The legislative history illustrates congressional intent to avoid delays in permit processing. S. Rep. No. 94–717, at 26 (1976) (“nothing could be more detrimental to the intent of this section and the integrity of this Act than to have the process encumbered by bureaucratic delay”). Thus, when read in combination, these 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. Accordingly, the EPA is seeking in this action to balance the requirements in the CAA to make a decision on a permit application within one year and to ensure that new and modified sources will only be authorized to construct after showing they can meet the substantive permitting criteria that apply to them. The EPA is achieving this balance by determining through rulemaking which O<sub>3</sub> NAAQS apply to certain permit applications that are pending when the EPA finalizes the revisions to the O<sub>3</sub> NAAQS in this final rule. We are clarifying, for the limited

purpose of satisfying the requirements under section 165(a)(3)(B) for those permits, which O<sub>3</sub> NAAQS are applicable to those permit applications and must be addressed in the source’s demonstration that its emissions do not cause or contribute to a violation of the NAAQS.

This approach is consistent with a recent opinion by the U.S. Court of Appeals for the Ninth Circuit, which recognized the EPA’s traditional exercise of grandfathering authority through rulemaking. The court observed that this approach was consistent with the 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). As discussed in more detail in the EPA’s Response to Comment Document contained in the docket for this rule, this case supports the EPA’s action in this rulemaking. The court favorably discussed prior adoption of regulatory grandfathering provisions that are similar to the action in this rulemaking, such as the grandfathering provision that the EPA promulgated when revising the PM<sub>2.5</sub> NAAQS that became effective in 2013. *See id.* at 982–83.<sup>227</sup>

This adoption of a grandfathering provision in this action is also consistent with previous actions in which the EPA has recognized that the CAA provides discretion for the EPA to establish grandfathering provisions for PSD permit applications through regulations. Some examples of previous

<sup>227</sup> This case specifically involved an action by the EPA to issue an individual PSD permit, which grandfathered a specific permit applicant from certain requirements without any revision to the regulations that were in effect. The court’s reasoning in this case distinguishes that type of permit-specific grandfathering from establishing grandfathering provisions through a rulemaking process. While the court was not persuaded that there was a conflict between the requirements of sections 165(a)(3) and 165(c) of the CAA that supported the permit-specific grandfathering at issue in that case, it did not extend that uncertainty to its discussion of the EPA’s rulemaking authority. In fact, in its favorable discussion of the EPA’s authority to grandfather pending permit applications through regulation, the court noted that the power of an administrative agency “to administer a congressionally created and funded program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress” though “such decision cannot be made on an ad hoc basis.” *Sierra Club v. EPA*, 762 F.3d 971, 983 (9th Cir. 2014) (internal quotations and marks omitted). This indicates that the court believed there is a gap in the CAA that supports including grandfathering provisions in regulations.

references to the EPA’s authority to grandfather certain applications through rulemaking include 45 FR 52683, August 7, 1980; 52 FR 24672, July 1, 1987; and most recently 78 FR 3086, January 15, 2013.

This grandfathering provision does not apply to any applicable PSD requirements related to O<sub>3</sub> other than the requirement to demonstrate that the proposed source does not cause or contribute to a violation of the revised O<sub>3</sub> NAAQS. Sources with projects qualifying under the grandfathering provision will be required to meet all the other applicable PSD requirements, including applying BACT to all applicable pollutants, demonstrating that emissions from the proposed facility will not cause or contribute to a violation of the O<sub>3</sub> NAAQS in effect at the time of the relevant grandfathering milestone, and addressing any Class I area and additional O<sub>3</sub>-related impacts in accordance with the applicable PSD requirements. In addition, this grandfathering provision would not apply to any permit application for a new or modified major stationary source of O<sub>3</sub> located in an area designated nonattainment for O<sub>3</sub> on the date the permit is issued.

## VIII. Implementation of the Revised O<sub>3</sub> Standards

This section provides background information for understanding the implications of the revised O<sub>3</sub> NAAQS 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 rules, interpretations of CAA requirements, and other EPA guidance relevant to implementation of the revised O<sub>3</sub> NAAQS. Relevant CAA provisions that provide potential flexibility with regard to meeting implementation timelines are highlighted and discussed. This section also contains a discussion of how existing requirements to reduce the impact on O<sub>3</sub> concentrations from the stationary source construction in permit programs under the CAA are affected by the revisions to the O<sub>3</sub> NAAQS. These are the PSD and Nonattainment New Source Review (NNSR) programs. As discussed in section VII of this preamble, to facilitate a smooth transition to the PSD requirements for the revised O<sub>3</sub> NAAQS, the EPA is finalizing as part of this rulemaking a grandfathering provision that applies to certain PSD permit applications that are pending and have met certain milestones in the permitting process

when the revised O<sub>3</sub> NAAQS is signed or before the effective date of the revised O<sub>3</sub> NAAQS, depending on the milestone.

In the preamble for the O<sub>3</sub> NAAQS proposal, the EPA solicited comments on several issues related to implementing the revised O<sub>3</sub> NAAQS that the agency anticipated addressing in future guidance or regulatory actions, but for which the EPA was not at that time proposing any action. The EPA received numerous comments on those and other implementation issues. Consistent with what the EPA indicated in the O<sub>3</sub> NAAQS proposal (79 FR 75370), the agency is not responding to the implementation comments that are not related to a specific proposal. However, the EPA intends to take these comments under advisement as the agency develops rules and guidance to assist with implementation of the revised NAAQS. Because the EPA did specifically propose and is finalizing provisions in the regulations addressing grandfathering for certain PSD permit applications and requirements, as discussed in section VII of this preamble, the EPA is responding to comments on the proposed PSD grandfathering provisions.

#### A. NAAQS Implementation Plans

##### 1. Cooperative Federalism

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 specific areas into attainment. The agency supports implementation planning with technical resources, guidance, and program rules where necessary, while air quality management 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<sub>3</sub> standards more than three decades ago. For example, 101 areas were designated as nonattainment for the 1-hour O<sub>3</sub> standards issued in 1979. As of the end of 2014, air quality in all but one of those areas meets the 1-hour standards. The EPA strengthened the O<sub>3</sub> standards in 1997, shifting to an 8-hour standard to improve public health protection, particularly for children, the elderly,

and other sensitive individuals. 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<sub>3</sub>-forming pollutants, significant progress has been made. Air quality in 108 of the original 115 areas designated as nonattainment for the 1997 O<sub>3</sub> NAAQS now meets those standards. Air quality in 18 of the original 46 areas designated as nonattainment for the 2008 O<sub>3</sub> NAAQS now meets those standards.

The revisions to the primary and secondary O<sub>3</sub> NAAQS discussed in sections II.D and IV.D of this preamble trigger a process under which states<sup>228</sup> make recommendations to the Administrator regarding area designations. Then, the EPA promulgates the final area designations. States also are required to review capacity and authorities in their existing SIPs to ensure the CAA requirements associated with the new standards can be carried out, and modify or supplement their existing SIPs as needed. The O<sub>3</sub> NAAQS revisions also apply to the transportation conformity and general conformity determinations, and affect which preconstruction permitting requirements apply to sources of O<sub>3</sub> precursor emissions, and the nature of those requirements.

The EPA has regulations in place addressing the general requirements for SIPs, and there are also provisions in these existing rules that cover O<sub>3</sub> SIPs (40 CFR part 51). States likewise have provisions in their existing SIPs to address air quality for O<sub>3</sub> and to implement the existing O<sub>3</sub> NAAQS. In the course of the past 45 years of regulating criteria pollutants, including O<sub>3</sub>, the EPA has also provided general guidance on the development of SIPs and administration of construction permitting programs, as well as specific guidance on implementing the O<sub>3</sub> NAAQS in some contexts under the CAA and the EPA regulations.

The EPA has considered the extent to which existing EPA regulations and guidance are sufficient to implement the revised standards. The CAA does not require that the EPA promulgate new implementing regulations or issue new guidance for states 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. It is important to note that the existing EPA regulations in 40 CFR part 51 applicable to SIPs generally and to particular pollutants, including O<sub>3</sub> and O<sub>3</sub> precursors, continue to apply unless and until they are updated.

Accordingly, the discussion below provides the EPA's current thoughts about the extent to which revisions to existing regulations and additional guidance are appropriate to aid in the implementation of the revised O<sub>3</sub> NAAQS.

##### 2. Additional New Rules and Guidance

The EPA has 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. As explained above, and consistent with the proposal, the EPA is not responding to these comments at this time because they are not related to any changes to existing regulations that EPA proposed in this rule. Moreover, 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 develop appropriate revisions to necessary implementation rules and provide additional guidance in time frames that are useful to states when developing implementation plans that meet CAA requirements.

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<sub>3</sub> NAAQS, the EPA is finalizing a grandfathering provision similar to the provision finalized in the 2012 PM<sub>2.5</sub> NAAQS Rule. See section VII.C of this preamble for more details on the PSD program and the final grandfathering provision.

Promulgation or revision 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 promulgating or revising the NAAQS. In an effort to allow states to make more informed recommendations for these particular standards, the EPA intends to issue additional guidance concerning the designations process for these standards within four months of promulgation of the NAAQS, or approximately eight months before state recommendations are due. The EPA generally completes

<sup>228</sup>This and all subsequent references to "state" are meant to include state, local, and tribal agencies responsible for the implementation of an O<sub>3</sub> control program.

area designations two years after promulgation of a NAAQS. See section VIII.B of this preamble for additional information on the initial area designation process.

Under CAA section 110, a NAAQS revision triggers the review and, as necessary, revision of SIPs to be submitted within three 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.<sup>229</sup> It should be noted that this guidance did not address certain state planning and emissions control requirements related to interstate pollution transport. This guidance remains relevant for the revised O<sub>3</sub> NAAQS. See section VIII.A.4 of this preamble for additional information on infrastructure SIPs.

While much of the existing rules and guidance for prior ozone standards remains applicable to the new standards, the EPA intends to propose to adopt revised rules on some subjects to facilitate air agencies’ efforts to implement the revised O<sub>3</sub> NAAQS within one year after the revised NAAQS is established. The rules would address nonattainment area classification methodologies and attainment dates, attainment plan and NNSR SIP submission due dates, and any other necessary revisions to existing regulations for other required implementation programs. The EPA anticipates finalizing these rules by the time areas are designated nonattainment. Finalizing rules and guidance on these subjects by this time would assist air quality management agencies with development of any CAA-required SIPs associated with nonattainment areas. See section VIII.A.5 of this preamble for additional information on nonattainment SIPs and section VIII.C.3 for additional information on nonattainment New Source Review requirements applicable to new major sources and major modifications of existing sources.

### 3. Background O<sub>3</sub>

The EPA and state, local and tribal air agencies, strive 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<sub>3</sub>. In most cases, reducing man-made emissions of NO<sub>x</sub> and VOCs within the U.S. will reduce O<sub>3</sub> formation and provide additional health and welfare protection. The EPA recognizes, however, that there can be infrequent events where daily maximum 8-hour O<sub>3</sub> concentrations approach or exceed 70 ppb largely due to the influence of wildfires or stratospheric intrusions, which contribute to U.S. background (USB) levels but may also qualify for consideration under the Exceptional Events Rule. See section I.D; but see section II.A.2.a above (percentage of anthropogenic O<sub>3</sub> tends to increase on high O<sub>3</sub> days relative to percentage of background, including in intermountain west).

The term “background” O<sub>3</sub> is often used to refer to O<sub>3</sub> that originates from natural sources of O<sub>3</sub> (e.g., wildfires and stratospheric O<sub>3</sub> intrusions) and O<sub>3</sub> precursors, as well as from man-made international emissions of O<sub>3</sub> precursors. Using the term generically, however, can lead to confusion as to what sources of O<sub>3</sub> are being considered. Relevant to the O<sub>3</sub> implementation provisions of the CAA, we define background O<sub>3</sub> the same way the EPA defines USB: O<sub>3</sub> that would exist in the absence of any man-made emissions inside the U.S.

While the great majority of modeled O<sub>3</sub> exceedances have local and regional emissions as their primary cause, there can be events where O<sub>3</sub> levels approach or exceed the concentration level of the revised O<sub>3</sub> standards in large part due to background sources. These cases of high USB levels on high O<sub>3</sub> days typically result from stratospheric intrusions of O<sub>3</sub> or wildfire O<sub>3</sub> plumes. These events are infrequent and the CAA contains provisions that can be used to help deal, in particular, with stratospheric intrusion and wildfire events with O<sub>3</sub> contributions of this magnitude, including providing varying degrees of regulatory relief for air agencies and potential regulated entities. The EPA intends to work closely with states to identify affected locations and ensure that the appropriate regulatory mechanisms are employed.

Statutory and regulatory relief associated with U.S. background O<sub>3</sub> may include:<sup>230</sup>

- 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 having to demonstrate attainment and having to adopt more than reasonable controls on local sources through international transport provisions.

Further discussion of these mechanisms is provided in sections VIII.B.2 (exceptional events), VIII.B.1 (rural transport areas), and VIII.E.2 (international transport).

Although these relief mechanisms require some level of assessment or demonstration by a state and/or the EPA to invoke, they have been used successfully in the past under appropriate circumstances. For example, the EPA has historically acted on every exceptional events demonstration that has affected a regulatory decision regarding initial area designations. See e.g., *Idaho: West Silver Valley Nonattainment Area—Area Designations for the 2012 primary annual PM<sub>2.5</sub> NAAQS Technical Support Document*, pp. 10–14, December 2014. For the revised O<sub>3</sub> standards, the areas that would most likely need to use the mechanisms discussed in this section as part of attaining the revised O<sub>3</sub> standards are locations in the western U.S. where we have estimated the largest seasonal average values of background O<sub>3</sub> occur. We expect some of these areas to use the provisions in the Exceptional Events Rule during the designations process for the revised O<sub>3</sub> standards. The EPA will then give priority to exceptional events demonstrations submitted by air agencies with areas whose designation decision could be influenced by the exclusion of data under the Exceptional Events Rule. In addition, as discussed in more detail in sections V.D and VIII.B.2 of this action, to streamline the exceptional events process, the EPA will soon propose revisions to the 2007 Exceptional Events Rule and will release through a **Federal Register** Notice of Availability a draft guidance document to address Exceptional Events Rule criteria for wildfires that could affect O<sub>3</sub> concentrations. We expect to

commenters pointed to remote monitored locations having O<sub>3</sub> exceedances due to background O<sub>3</sub> in fact reflected sizeable contributions from domestic sources, including interstate contributions (including from the Los Angeles Basin and other California locations).

<sup>229</sup> 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, which is available at [http://www3.epa.gov/airquality/urbanair/sipstatus/docs/Guidance\\_on\\_Infrastructure\\_SIP\\_Elements\\_Multipollutant\\_FINAL\\_Sept\\_2013.pdf](http://www3.epa.gov/airquality/urbanair/sipstatus/docs/Guidance_on_Infrastructure_SIP_Elements_Multipollutant_FINAL_Sept_2013.pdf).

<sup>230</sup> 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<sub>3</sub> and O<sub>3</sub> precursor emissions from man-made sources within the continental U.S. rather than background O<sub>3</sub> as it is defined in this section. As noted in section II.A.2.a above, many of the instances where

promulgate Exceptional Events Rule revisions and finalize the new guidance document before the October 2016 date by which states, and any tribes that wish to do so, are required to submit their initial designation recommendations for the revised O<sub>3</sub> NAAQS.

#### 4. Section 110 State Implementation Plans

The CAA section 110 specifies the general requirements for SIPs. Within three years after the promulgation of revised NAAQS (or such shorter period as the Administrator may prescribe<sup>231</sup>) 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 SIP" submissions establish the basic state programs to implement, maintain, and enforce revised NAAQS and provide assurances of state resources and authorities. States are required 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. Because the revised primary NAAQS and secondary NAAQS are identical, the EPA does not at present discern any need for there to be any significant substantive difference in the infrastructure SIP elements for the two standards and thus 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 three years of promulgation of the O<sub>3</sub> NAAQS). Accordingly the EPA is not extending the SIP deadline for purposes of a revised secondary standard.

It is the responsibility of each state to review its air quality management program's compliance with the infrastructure SIP provisions in light of each new or revised NAAQS. Most states have revised and updated their infrastructure SIPs in recent years to address requirements associated with the 2008 O<sub>3</sub> NAAQS. We expect that the result of these prior updates is that, in most cases, states will already have adequate state regulations previously adopted and approved into the SIP to address a particular requirement with respect to the revised O<sub>3</sub> NAAQS. For

such portions of the state's infrastructure SIP submission, the state may provide a "certification" specifying that certain existing provisions in the SIP are adequate to meet applicable requirements. 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<sub>3</sub> 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 submission 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 submission, 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 submission 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. In the event that a state's existing SIP does not already meet applicable requirements, then the infrastructure SIP submission must include the modifications or additions to the state's SIP in order to update it to meet the relevant elements of section 110(a)(2).

#### 5. Nonattainment Area Requirements

Part D of the CAA describes the various program requirements that apply to states with nonattainment areas for different NAAQS. Clean Air Act Section 182 (found in subpart 2 of part D) includes the specific SIP requirements that govern the O<sub>3</sub> program, and supplements the more general nonattainment area requirements in CAA sections 172 and 173. Under CAA section 182, states

generally are required to submit attainment demonstration SIPs within three or four years after the effective date of area designations promulgated by the EPA, depending on the classification of the area.<sup>232</sup> These SIP submissions need to show how the nonattainment area will attain the primary O<sub>3</sub> 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.

The EPA believes that the overall framework and policy approach of the implementation rules associated with the 2008 O<sub>3</sub> NAAQS provide an effective and appropriate template for the general approach states would follow in planning for attainment of the revised O<sub>3</sub> standard.<sup>233</sup> However, to assist with the implementation of the revised O<sub>3</sub> standards, the EPA intends to develop and propose an additional O<sub>3</sub> NAAQS Implementation Rule that will address certain subjects specific to the new O<sub>3</sub> NAAQS finalized here. This will include establishing air quality thresholds associated with each nonattainment area classification (*i.e.*, Marginal, Moderate, etc.), associated attainment deadlines, and deadlines for submitting attainment planning SIP elements (*e.g.*, RACT for major sources, RACT VOC control techniques guidelines, etc.). The rulemaking will also address whether to revoke the 2008 O<sub>3</sub> NAAQS, and to impose appropriate anti-backsliding requirements to ensure that the protections afforded by that standard are preserved. The EPA intends to propose this implementation rule within one year after the revised O<sub>3</sub> NAAQS is promulgated, and finalize this implementation rule by no later than the time the area designations process is finalized (approximately two years after promulgation of the revised O<sub>3</sub> NAAQS).

We know that developing the implementation plans that outline the steps a nonattainment area will take to

<sup>232</sup> Section 181(a)(1) of the CAA establishes classification categories for areas designated nonattainment for the primary O<sub>3</sub> NAAQS. These categories range from "Marginal," the lowest O<sub>3</sub> classification with the fewest requirements associated with it, to "Extreme," the highest classification with the most required programs. Areas with worse O<sub>3</sub> problems are given more time to attain the NAAQS and more associated emission control requirements.

<sup>233</sup> Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements; Final Rule (80 FR 12264; March 6, 2015) and Implementation of the 2008 National Ambient Air Quality Standards for Ozone: Nonattainment Area Classifications Approach, Attainment Deadlines and Revocation of the 1997 Ozone Standards for Transportation Conformity Purposes (77 FR 30160; May 21, 2012).

<sup>231</sup> 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 for this revision to the O<sub>3</sub> NAAQS.

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 attainment demonstrations.

### B. O<sub>3</sub> Air Quality Designations

#### 1. Area Designation Process

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 meet or do not meet the new or revised NAAQS, along with any nearby areas that contribute to areas that do not meet the new or revised NAAQS.

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 state's initial recommendation.

Clean Air Act 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." 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.<sup>234</sup>

As discussed in sections II and IV of this preamble, the EPA is revising both the primary and secondary O<sub>3</sub> NAAQS. Accordingly, the EPA intends to complete designations for both NAAQS following the standard 2-year process discussed above. In accordance with section 107(d)(1) of the CAA, state Governors (and tribes, if they choose) should submit their initial designation recommendations for a revised primary and secondary NAAQS by 1 year after 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 the 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.

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. Consistent with previous area designations processes, the EPA intends to use area-specific analysis of multiple factors to support area boundary decisions. The EPA intends to evaluate information related to the following factors for designations: air quality data, emissions and emissions-related data, meteorology, geography/topography, and jurisdictional boundaries. Additional guidance on the designation process and how these factors may be evaluated and inform the process will be issued by the EPA early in 2016 to assist states in developing their recommendations.

<sup>234</sup> 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/20120117naaqs\\_guidance.pdf](http://www.epa.gov/ttn/oarpg/t1/memoranda/20120117naaqs_guidance.pdf).

Areas that are designated as nonattainment are also classified at the time of designation by operation of law according to the severity of their O<sub>3</sub> problem. The classification categories are Marginal, Moderate, Serious, Severe, and Extreme. Ozone nonattainment areas are subject to specific mandatory measures depending on their classification. As indicated previously, the thresholds for the classification categories will be established in a future O<sub>3</sub> implementation rule.

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. Regardless of its classification, a rural transport area is deemed to have fulfilled all O<sub>3</sub>-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. 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<sub>3</sub> concentrations in the area, or in other areas; and
- The area does not include and is not adjacent to a Metropolitan Statistical Area.

Historically, the EPA has listed four nonattainment areas as rural transport areas under this statutory provision.<sup>235</sup> 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<sub>3</sub> and/or O<sub>3</sub> precursors into the area is so overwhelming that the contribution of local emissions to an observed 8-hour O<sub>3</sub> 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<sub>3</sub> concentrations measured in the area or in other areas.<sup>236</sup> While this guidance

<sup>235</sup> For the 1979 1-hour O<sub>3</sub> standard, Door County Area, Wisconsin; Edmonson County Area, Kentucky; Essex County Area (Whiteface Mountain), New York; and Smyth County Area (White Top Mountain), Virginia were recognized by the EPA as rural transport areas. No rural transport areas were recognized for the 1997 or 2008 8-hour O<sub>3</sub> standards.

<sup>236</sup> 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://>



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<sub>3</sub> nonattainment area as a rural transport area. The EPA will work with states to ensure nonattainment areas eligible for treatment as rural transport areas are identified.

## 2. Exceptional Events

During the initial area designations process, the EPA intends to evaluate multiple factors, including air quality data, when identifying and determining boundaries for areas of the country that meet or do not meet the revised O<sub>3</sub> NAAQS. In some cases, these data may be influenced by exceptional events. Under the Exceptional Events Rule, an air agency can request and the EPA can agree to exclude data associated with event-influenced exceedances or violations of a NAAQS, including the revised O<sub>3</sub> NAAQS, provided the event meets the statutory requirements in section 319(b) of the CAA, which requires that:

- 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,”<sup>237</sup> and
- that “a clear causal relationship must exist between the measured exceedances of a [NAAQS] and the exceptional event. . . .”

The EPA’s implementing regulations, the Exceptional Events Rule, further specify certain requirements for air agencies making exceptional events demonstrations.<sup>238</sup>

The ISA contains discussions of natural events that may contribute to O<sub>3</sub> or O<sub>3</sub> precursors. These include stratospheric O<sub>3</sub> intrusion and wildfire events.<sup>239</sup> As indicated above, to satisfy the exceptional events requirements and to qualify for data exclusion under the Exceptional Events Rule, an air agency must develop and submit a

demonstration, including evidence, addressing each of the identified criteria. The extent to which a stratospheric O<sub>3</sub> intrusion event or a wildfire event contributes to O<sub>3</sub> levels can be uncertain, and in most cases requires detailed analyses to determine.

Strong stratospheric O<sub>3</sub> 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<sub>3</sub> based on ambient measurements. Accurately determining the extent of weaker intrusion events remains challenging (U.S. EPA 2013, p. 3–34). Although states have submitted only a few exceptional events demonstrations for stratospheric O<sub>3</sub> intrusion, the EPA recently approved a demonstration from Wyoming for a June 2012 stratospheric O<sub>3</sub> event.<sup>240</sup>

While stratospheric O<sub>3</sub> intrusions can increase monitored ground-level ambient O<sub>3</sub> concentrations, wildfire plumes can either suppress or enhance O<sub>3</sub> 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 a result, determining the impact of wildfire emissions on specific O<sub>3</sub> observations is challenging. The EPA recently approved an exceptional events demonstration for wildfires affecting 1-hour O<sub>3</sub> 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<sub>3</sub> data affected by large fires.<sup>241</sup>

In response to previously expressed stakeholder feedback regarding implementation of the Exceptional Events Rule and specific stakeholder concerns regarding the burden of exceptional events demonstrations, the EPA is currently engaged in a rulemaking process to amend the Exceptional Events Rule. As part of an upcoming notice and comment rulemaking effort (and related activities, including the issuance of relevant guidance documents), the EPA sees opportunities to standardize best

practices for collaboration between the EPA and air agencies, clarify and simplify demonstrations, and improve tools and consistency.

Additionally, the EPA intends to develop guidance to address implementing the Exceptional Events Rule criteria for wildfires that could affect ambient O<sub>3</sub> concentrations. Wildfire emissions are a component of background O<sub>3</sub> (Jaffe and Wigder, 2012) and in some locations can significantly contribute to periodic high O<sub>3</sub> levels (Emery, 2012). The threat from wildfires can be mitigated through management of wildland vegetation. Planned and managed fires are one tool that land managers can use to reduce fuel load, unnatural understory and tree density, thus helping to reduce the risk of catastrophic wildfires. Allowing some wildfires to continue and the thoughtful use of prescribed fire can influence the occurrence of catastrophic wildfires, which may reduce the probability of fire-induced smoke impacts and subsequent health effects. Thus, appropriate use of prescribed fire may help manage the contribution of wildfires to both background and periodic peak O<sub>3</sub> air pollution. Several commenters expressed concern that the revised O<sub>3</sub> NAAQS could limit the future use of prescribed fire. Under the current Exceptional Events Rule, prescribed fires meeting the rule criteria may also qualify as exceptional events. The EPA intends to further clarify the Exceptional Events Rule criteria for prescribed fire on wildland in its upcoming rulemaking.

The EPA is committed to working with federal land managers, other federal agencies, tribes and states to effectively manage prescribed fire use to reduce the impact of wildfire-related emissions on O<sub>3</sub> through policies and regulations implementing these standards.

### C. How do the New Source Review (NSR) requirements apply to the revised O<sub>3</sub> NAAQS?

#### 1. NSR Requirements for Major Stationary Sources for the Revised O<sub>3</sub> NAAQS

The CAA, at parts C and D of title I, contains 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 stationary source and major modification applies on a pollutant-specific basis, and the requirements that apply for each pollutant depend on whether the area in which the source is situated is designated as attainment (or

[www.epa.gov/scram001/guidance/guide/owt\\_guidance\\_07-13-05.pdf](http://www.epa.gov/scram001/guidance/guide/owt_guidance_07-13-05.pdf).

<sup>237</sup> 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.”

<sup>238</sup> 72 FR 13,560 (March 22, 2007), “Treatment of Data Influenced by Exceptional Events,” Final Rule; see also 40 CFR parts 50 and 51.

<sup>239</sup> The preamble to the Exceptional Events Rule (72 FR 13560) identifies both stratospheric O<sub>3</sub> intrusions and wildfires as natural events that could also qualify as exceptional events under the CAA and Exceptional Event Rule criteria. Note that O<sub>3</sub> 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.

<sup>240</sup> 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>.

<sup>241</sup> 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<sub>3</sub>-related exceptional event submissions, available at <http://www.epa.gov/ttn/analysis/exevents.htm>.

unclassifiable) or nonattainment for that pollutant. In areas designated attainment or unclassifiable for a pollutant, the PSD requirements under part C apply to construction at major sources. In areas designated nonattainment for a pollutant, the NNSR requirements under part D apply to major source construction. Collectively, those two sets of permit requirements are commonly referred to as the “major New Source Review” or “major NSR” programs.

Until an area is formally designated with respect to the revised O<sub>3</sub> NAAQS, the NSR provisions applicable under that area’s current designation for the 2008 O<sub>3</sub> NAAQS (including any applicable anti-backsliding requirements) will continue to apply. That is, for areas designated as attainment/unclassifiable for the 2008 O<sub>3</sub> NAAQS, PSD will apply for new major stationary sources and major modifications that trigger major source permitting requirements for O<sub>3</sub>; areas designated nonattainment for the 2008 O<sub>3</sub> NAAQS must comply with the NNSR requirements for new major stationary sources and major modifications that trigger major source permitting requirements for O<sub>3</sub>. When the new designations for the revised O<sub>3</sub> NAAQS become effective, under the current rules, those designations will generally serve to determine whether PSD or NNSR applies to O<sub>3</sub> and its precursors. The PSD regulations at 40 CFR 51.166(i)(2) and 52.21(i)(2) provide that the substantive PSD requirements do not apply for a particular pollutant if the owner or operator of the new major stationary source or major modification demonstrates that the area in which the source is located is designated 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<sub>3</sub> if they are locating in an area that does not have a current nonattainment designation under CAA section 107 for O<sub>3</sub>. These rules further provide that nonattainment designations for a revoked NAAQS, as contained in 40 CFR part 81, are not viewed as current designations under CAA section 107 for purposes of determining the applicability of such PSD requirements.<sup>242</sup>

The EPA’s major NSR regulations define the term “regulated NSR pollutant” to include any pollutant for which a NAAQS has been promulgated

and any pollutant identified in EPA regulations as a constituent or precursor to such pollutant.<sup>243</sup> Both the PSD and NNSR regulations identify VOC and NO<sub>x</sub> as precursors to O<sub>3</sub>. Accordingly, the major NSR programs for O<sub>3</sub> are applied to emissions of VOC and NO<sub>x</sub> as precursors of O<sub>3</sub>.<sup>244</sup>

## 2. Prevention of Significant Deterioration (PSD) Program

The statutory requirements for a PSD permit program set forth under part C of title I of the CAA (sections 160 through 169) are addressed by the EPA’s PSD regulations found at 40 CFR 51.166 (minimum requirements for an approvable PSD SIP) and 40 CFR 52.21 (PSD permitting program for permits issued under the EPA’s federal permitting authority). Both sets of regulations already apply for O<sub>3</sub> when the area is designated attainment or unclassifiable for O<sub>3</sub> and when the new source or modification triggers PSD requirements for O<sub>3</sub>.

For PSD, a “major stationary source” is one that emits or has 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 that emits or has 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 for the project, and second, in a significant net emissions increase of that pollutant at the source. *See* 40 CFR 51.166(b)(2)(i), 40 CFR 52.21(b)(2)(i).

Among other things, for each regulated NSR pollutant emitted or increased in significant amounts, the PSD program requires a new major stationary source or a major modification to apply Best Available Control Technology 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)). The PSD requirements may also include, in appropriate cases, an analysis of potential adverse impacts on Class I areas (*see* CAA sections 162 and 165).<sup>245</sup> The EPA has generally interpreted the requirement for an air quality impact analysis under CAA section 165(a)(3) and the implementing regulations to include a requirement to demonstrate that emissions from the proposed facility will not cause or contribute to a violation of any NAAQS that is in effect as of the date a PSD permit is issued.<sup>246</sup> *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, the demonstration required under CAA section 165(a)(3) and 40 CFR 51.166(k) and 52.21(k) will apply to any revised O<sub>3</sub> 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. In addition, the other existing requirements of the PSD program will remain applicable to O<sub>3</sub> after the revised O<sub>3</sub> NAAQS takes effect.

Because the complex chemistry of O<sub>3</sub> formation in the atmosphere poses significant challenges for the assessing the impacts of individual stationary sources on O<sub>3</sub> formation, the EPA’s judgment historically has been that it is not technically sound to designate a

<sup>245</sup> 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.

<sup>246</sup> An exception occurs in cases where the EPA has included a grandfathering provision in its PSD regulations for a particular pollutant. The EPA historically has exercised its discretion to transition the implementation of certain new requirements through grandfathering, under appropriate circumstances, either by rulemaking or through a case-by-case determination for a specific permit application. In 2014, the United States Court of Appeals for the Ninth Circuit 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. This decision is addressed in more detail in the discussion of the grandfathering provisions that the EPA is issuing through this rulemaking in section VII of this preamble.

<sup>243</sup> The definition of “regulated NSR pollutant” is found in the PSD regulations at 40 CFR 51.166(b)(49) and 52.21(b)(50), and in the NNSR regulations at 40 CFR 51.165(a)(1)(xxxvii).

<sup>244</sup> VOC and NO<sub>x</sub> are defined as precursors of ozone in the PSD regulations at 40 CFR 51.166(b)(49)(i)(b)(1) and 52.21(b)(50)(i)(b)(1), and in the NNSR regulations at 40 CFR 51.165(a)(1)(xxxvii)(B) and (C)(1) and part 51, Appendix S, II.A.31(ii)(b)(1).

<sup>242</sup> This description of paragraph (i)(2) of the PSD regulations at 40 CFR 51.166 and 52.21 reflects revisions made in the final 2008 O<sub>3</sub> NAAQS SIP Requirements Rule. *See* 80 FR 12264 at 12287 (March 6, 2015).

specific air quality model that must be used in the PSD permitting process to make this demonstration for O<sub>3</sub>. To address ambient impacts of emissions from proposed individual stationary sources on O<sub>3</sub>, the EPA proposed amendments to Appendix W to 40 CFR part 51 in July 2015 that would, among other things, revise the Appendix W provisions relating to the analytical techniques for demonstrating that an individual PSD source or modification does not cause or contribute to a violation of the O<sub>3</sub> NAAQS (80 FR 45340, July 29, 2015). Until any revisions are finalized and in effect, PSD permit applicants should continue to follow the current provisions in the applicable regulations and Appendix W in order to demonstrate that a proposed source or modification does not cause or contribute to a violation of the O<sub>3</sub> NAAQS.

a. What transition plan is the EPA providing for implementing the PSD requirements for the revised O<sub>3</sub> NAAQS?

In this rulemaking, the EPA is amending the PSD regulations at 40 CFR 51.166 and 40 CFR 52.21 to include a grandfathering provision that will allow reviewing authorities to continue to review certain pending PSD permit applications in accordance with the O<sub>3</sub> NAAQS that was in effect when a specific permitting milestone was reached, rather than the revised O<sub>3</sub> NAAQS. The EPA is finalizing the grandfathering provision as proposed with two trigger dates—the signature date of the revised O<sub>3</sub> NAAQS rule for complete applications and the effective date of the revised O<sub>3</sub> NAAQS for a draft permit or preliminary determination. A more detailed discussion of the final provision, comments received and our responses to those comments is provided in section VII of this preamble, which addresses this change to the PSD regulations, as well as the Response to Comment Document contained in the docket for this rulemaking.

b. What screening and compliance demonstration tools are used to implement the PSD program?

The EPA has historically allowed the use of screening and compliance demonstration tools to help facilitate the implementation of the NSR program by reducing the source's burden and streamlining the permitting process for circumstances where the emissions or ambient impacts of a particular pollutant could be considered *de minimis*. For example, the EPA has established significant emission rates, or SERs, that are used as screening tools to

determine when a pollutant would be considered to be emitted in a significant amount and, accordingly, when the NSR requirements should be applied to that pollutant. See 40 CFR 51.166(b)(23) and 52.21(b)(23). For O<sub>3</sub>, the EPA established a SER of 40 tpy for emissions of each O<sub>3</sub> precursor—VOC and NO<sub>x</sub>. For PSD, the O<sub>3</sub> SER applies independently to emissions of VOC and NO<sub>x</sub> (emissions of precursors are not added together) to determine when the proposed major stationary source or major modification must undergo PSD review for that precursor and whether individual PSD requirements, such as BACT, apply to that precursor.<sup>247</sup>

In the context of the PSD air quality impact analysis, the EPA has also used a value called a significant impact level (SIL) as a compliance demonstration tool. The SIL, expressed as an ambient concentration of a pollutant, may be used first to determine the geographical scope of the ambient impact analysis that must be completed for the applicable pollutant to satisfy the air quality demonstration requirement under CAA section 165(a)(3). A second use is to guide the determination of whether the impact of the source is considered to cause or contribute to a violation of any NAAQS. The EPA has not established a SIL for O<sub>3</sub>. The EPA is currently considering development of a SIL for O<sub>3</sub> through either guidance or a rulemaking process. Such a SIL would complement proposed revisions to Appendix W mentioned above (80 FR 45340, July 29, 2015) and would assist in the implementation of the PSD air quality analysis requirement for protection of the O<sub>3</sub> NAAQS. However, the EPA is not making revisions in this rulemaking to address the PSD air quality analysis for O<sub>3</sub>. Until any rulemaking to amend existing PSD regulations for O<sub>3</sub> is completed, permitting decisions should continue to be based on the existing provisions in the applicable regulations.

Several commenters addressed statements that the EPA made concerning screening tools for O<sub>3</sub> in the preamble to the O<sub>3</sub> NAAQS proposal. These statements were not linked to any proposed amendments to EPA regulations. Aside from adopting the grandfathering provision addressed in section VII of this preamble, the EPA is not revising the PSD requirements for O<sub>3</sub> in this final rule. Therefore, the EPA

<sup>247</sup> See *In re Footprint Power Salem Harbor Development, LP*, 16 E.A.D. \_\_\_, PSD Appeal No. 14–02, at 20–25 (EAB, Sept. 2, 2014) (including description of EPA's position on application of BACT to ozone precursors) available at [http://yosemite.epa.gov/oa/EAB\\_Web\\_Docket.nsf/PSD+Permit+Appeals+\(CAA\)?OpenView](http://yosemite.epa.gov/oa/EAB_Web_Docket.nsf/PSD+Permit+Appeals+(CAA)?OpenView).

is not responding to those comments at this time, consistent with the EPA's general approach to comments on implementation topics described above.

c. Other PSD Transition Issues

The EPA anticipates that the existing O<sub>3</sub> air quality in some areas currently designated attainment or unclassifiable for O<sub>3</sub> will not meet the revised O<sub>3</sub> NAAQS upon its effective date and that some of these areas will ultimately be designated “nonattainment” for the revised O<sub>3</sub> NAAQS through the formal area designation process set forth under the CAA (see section VIII.B above). However, until the EPA issues such nonattainment designations, proposed new major sources and major modifications situated in any area designated attainment or unclassifiable for the 2008 O<sub>3</sub> NAAQS will continue to be required to address O<sub>3</sub> in a PSD permit.<sup>248</sup> As mentioned above, the PSD permitting program requires that proposed new major stationary sources and major modifications must demonstrate that the emissions from the proposed source or modification will not cause or contribute to a violation of any NAAQS. In the notice of proposed rulemaking, the EPA provided information concerning its views on the possibility that some PSD permit applications could satisfy the air quality analysis requirements for O<sub>3</sub> by obtaining air quality offsets (called PSD offsets).<sup>249</sup> Several commenters expressed concern that without some transition provisions in the final rule exempting PSD permit applications for sources located in such areas from meeting the air quality analysis requirements for the revised O<sub>3</sub> NAAQS, such applications might not be able to satisfy the demonstration requirement, as the current ambient air monitoring data indicate the revised lower standards are not being met. The O<sub>3</sub> NAAQS proposal included no proposed revisions to PSD regulations on this

<sup>248</sup> Any proposed major stationary source or major modification subject to PSD for O<sub>3</sub> that does not receive its PSD permit by the effective date of a new O<sub>3</sub> 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<sub>3</sub>, even if such source had been grandfathered under the PSD regulations from the demonstration requirement under CAA section 165(a)(3) for O<sub>3</sub>.

<sup>249</sup> The EPA has historically recognized in regulations and through other actions that sources applying for PSD permits may have the option of utilizing offsets as part of the required PSD demonstration under CAA section 165(a)(3)(B). 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).

topic and the EPA is not making any revisions to the PSD requirements for O<sub>3</sub> in this action to address this issue. Therefore, the EPA is not responding to those comments at this time, consistent with its general approach to comments on implementation topics described above. However, to help address this concern raised by commenters, the EPA is considering issuing additional guidance on how PSD offsets can be implemented.

### 3. Nonattainment NSR

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. The relevant part D requirements are typically referred to as the nonattainment NSR (NNSR) program. The EPA regulations for the NNSR program are contained at 40 CFR 51.165, 52.24 and part 51 Appendix S. The EPA's minimum requirements for a NNSR program to be approvable into a SIP are contained in 40 CFR 51.165. Appendix S to 40 CFR part 51 contains an interim NNSR program. This interim program enables implementation of NNSR permitting in nonattainment areas that lack a SIP-approved NNSR permitting program for the particular nonattainment pollutant, and the interim program can be applied during the time between the date of the relevant nonattainment designation and the date on which the EPA approves into the SIP a NNSR program or additional components of an NNSR program for a particular pollutant.<sup>250</sup> This interim program is commonly known as the Emissions Offset Interpretative Rule, and is applicable to all criteria pollutants, including O<sub>3</sub>.<sup>251</sup>

The EPA is not modifying any existing NNSR requirements in this rulemaking. Under the CAA, area designations for new or revised NAAQS are addressed subsequent to the effective date of the new or revised NAAQS. If the EPA determines that any revisions to the existing NNSR requirements, including those in Appendix S, are appropriate, the EPA expects, at a later date contemporaneous with the designation process for the revised O<sub>3</sub> NAAQS, to propose those revisions. If any changes are proposed to Appendix S requirements, the EPA

anticipates that it would intend for those changes to become effective no later than the effective date of the area designations. This timing would allow air agencies that lack an approved NNSR program for O<sub>3</sub> to use the relevant Appendix S provisions to issue NNSR permits addressing O<sub>3</sub> on and after the effective date of designations of new nonattainment areas for O<sub>3</sub> until such time as a NNSR program for O<sub>3</sub> is approved into the SIP.<sup>252</sup>

For NNSR, new major stationary sources and major modifications for O<sub>3</sub> must comply with the Lowest Achievable Emission Rate (LAER) requirements as defined in the CAA and NNSR rules, and must perform other analyses and satisfy other requirements under section 173 of the CAA. For example, under CAA section 173(c) emissions reductions, known as emissions offsets, must be secured to offset the increased emissions of the air pollutant (including the relevant precursors) from the new or modified source by an equal or greater reduction, as applicable, of such pollutant. The appropriate emissions offset needed for a particular source will depend upon the classification for the O<sub>3</sub> nonattainment area in which the source or modification will locate, such that areas with more severe nonattainment classifications have more stringent offset requirements. This ranges from 1.1:1 for areas classified as Marginal to 1.5:1 for areas classified as Extreme. *See, e.g.*, CAA section 182, 40 CFR 51.165(a)(9) and 40 CFR part 51 Appendix S section IV.G.2.

To facilitate continued economic development in nonattainment areas, many states have established offset banks or registries.<sup>253</sup> Such banks or registries can help new or modified major stationary source owners meet offset requirements by streamlining identification and access to available emissions reductions. Some states have established offset banks to help ensure a consistent method for generating, validating and transferring NO<sub>x</sub> and VOC offsets. Offsets in these areas are generated by emissions reductions that meet specific creditability criteria set forth by the SIP consistent with the EPA regulations. *See* 40 CFR 51.165(a)(3)(ii)(A)-(J) and part 51 Appendix S section IV.C. The EPA

received comments expressing concern about the limited availability of offsets in nonattainment areas. Since the EPA did not propose, and is not finalizing, any amendments related to the NNSR offset provisions, the EPA is not responding to those comments at this time, consistent with the EPA's general approach to comment on implementation topics as described above.

### D. Transportation and General Conformity

#### 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<sub>3</sub> 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

<sup>250</sup> *See* Appendix S, Part I; 40 CFR 52.24(k).

<sup>251</sup> 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).

<sup>252</sup> States with SIP-approved NNSR programs for O<sub>3</sub> should evaluate that program to determine whether they can continue to issue permits under their approved program or whether revisions to their program are necessary to address the revised O<sub>3</sub> NAAQS.

<sup>253</sup> *See, for example*, emission reduction credit banking programs in Ohio (OAC Chapter 3745-1111) and California (H&SC Section 40709).

individual federal actions. More information on the general conformity program is available at <http://www.epa.gov/air/genconform/>.

2. When would transportation and general conformity apply to areas designated nonattainment for the revised O<sub>3</sub> NAAQS?

Transportation and general conformity apply one year after the effective date of nonattainment designations for the revised O<sub>3</sub> 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.

3. Impact of a Revised O<sub>3</sub> NAAQS on a State's Existing Transportation and/or General Conformity SIP

In this final rule, the EPA is revising the O<sub>3</sub> NAAQS, but is not making specific changes to its transportation or general conformity regulations. Therefore, states should not need to revise their transportation and/or general conformity SIPs. While we are not making any revisions to the general conformity regulations at this time, we recommend, when areas develop SIPs for a revised O<sub>3</sub> NAAQS, that state and local air quality agencies work with federal agencies with large emitting activities that are subject to the general conformity regulations to establish an emissions budget for those facilities and activities in order to facilitate future conformity determinations under the conformity regulations. Finally, states with existing conformity SIPs and new nonattainment areas may also need to revise their conformity SIPs in order to ensure the state regulations apply in any newly designated areas.

Because significant tracts of land under federal management may be included in nonattainment area boundaries, the EPA encourages state and local air quality agencies to work with federal agencies to assess and develop emissions budgets that consider emissions from projects subject to general conformity, including emissions from fire on wildland, in any baseline, modeling and SIP attainment inventory. Where appropriate, states, land managers, and landowners may also consider developing plans to ensure that fuel accumulations are addressed. Information is available from DOI and USDA Forest Service on the ecological role of fire and on smoke management

programs and basic smoke management practices.<sup>254</sup>

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>).

#### *E. Regional and International Pollution Transport*

##### 1. Interstate Transport

The CAA contains provisions that specifically address and require regulation of the interstate transport of air pollution that does not otherwise qualify for data exclusion under the Act's exceptional events provisions. As previously noted, emissions from events, such as wildfires, may qualify as exceptional events and may be transported across jurisdictional boundaries. The EPA intends to address the transport of event-related emissions in our upcoming proposed revisions to the Exceptional Events Rule and draft guidance document addressing the Exceptional Events Rule criteria for wildfires that could affect O<sub>3</sub> concentrations. The EPA encourages affected air agencies to coordinate with their EPA regional office to identify approaches to evaluate the potential impacts of transported event-related emissions and determine the most appropriate information and analytical methods for each area's unique situation.

CAA section 110(a)(2)(D)(i)(I), *Interstate Transport*—CAA section 110(a)(2)(D)(i)(I) requires states to develop and implement a SIP to address the interstate transport of emissions. Specifically, this provision requires the SIP to prohibit "any source or other type of emissions activity within the state" that would "significantly contribute to nonattainment" of any NAAQS in another state, or that would "interfere with maintenance" of any NAAQS in another state. When EPA promulgates or

revises a NAAQS, each state is required to submit a SIP addressing this interstate transport provision within 3 years.

CAA section 126, *Interstate Transport*—CAA section 126(b) provides states and political subdivisions with a mechanism to petition the Administrator for a finding that "any major source or group of stationary sources emits or would emit any air pollution in violation of the prohibition of [CAA section 110(a)(2)(D)(i)(I)]."<sup>255</sup> Where the EPA makes such finding, the source is allowed to operate beyond a 3-month period after such finding only if the EPA establishes emissions limitations and a compliance schedule designated to bring the source into compliance as expeditiously as practicable, but no later than three years after such finding. This mechanism is available to downwind states and political subdivisions, regardless of designation status, that would be affected by emissions from upwind states.

##### 2. International Transport

The agency is active in work to reduce the international transport of O<sub>3</sub> and other pollutants that can contribute to "background" O<sub>3</sub> 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. The U.S. has worked bilaterally with Canada under the US-Canada Air Quality Agreement to adopt an Ozone Annex to address transboundary O<sub>3</sub> impacts and continues to work with China on air quality management activities. This work includes supporting China's efforts to rapidly deploy power plant pollution controls that can achieve NO<sub>x</sub> reductions of at least 80 to 90%. The U.S. also continues to work bilaterally with Mexico on the Border 2020 program to support efforts to improve environmental conditions in the border region. One of the main goals of the program is to reduce air pollution, including emissions that can cause transboundary O<sub>3</sub> impacts.

<sup>254</sup> USDA Forest Service and Natural Resources Conservation Service, Basic Smoke Management Practices Tech Note, October 2011, [http://www.nrcs.usda.gov/Internet/FSE\\_DOCUMENTS/stelprdb1046311.pdf](http://www.nrcs.usda.gov/Internet/FSE_DOCUMENTS/stelprdb1046311.pdf).

<sup>255</sup> The text of section 126 codified in the United States Code cross references section 110(a)(2)(D)(ii) instead of section 110(a)(2)(D)(i). The courts have confirmed that this is a scrivener's error and the correct cross reference is to section 110(a)(2)(D)(i). See *Appalachian Power Co. v. EPA*, 249 F.3d 1032, 1040-44 (D.C. Cir. 2001).

Clean Air Act section 179B recognizes the possibility that certain nonattainment areas may be impacted by O<sub>3</sub> or O<sub>3</sub> 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<sub>3</sub> levels will be largest in locations that are in the immediate vicinity of an international border with Canada or Mexico. The science review also cites two recent studies which indicate that intercontinental transport of pollution, along with other natural sources and local pollutant sources, can affect O<sub>3</sub> air quality in the western U.S. under specific conditions. (U.S. EPA 2013, p. 3–140). Section 179B allows states to consider in their attainment plans and demonstrations whether an area might meet the O<sub>3</sub> 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 of the NAAQS in such an area impacted by international transport after adopting all reasonably available control measures (e.g., 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 and demonstration, and there would be no adverse consequence for a finding that the area failed to attain the NAAQS by the relevant attainment date. States can also avoid potential sanctions and FIPs that would otherwise apply for failure to submit a required SIP submission or failure to submit an approvable SIP submission. For example, section 179B explicitly provides that the area shall not be reclassified to the next highest classification or required to implement a section 185 penalty fee program if a state meets the applicable criteria.

Section 179B authority does not allow an area to avoid a nonattainment designation or for the area to be classified with a lower classification than is indicated by actual ambient air quality. 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 periodic emissions reduction progress requirements. In this way, section 179B insures that states will take actions to mitigate the public health impacts of exposure to ambient levels of pollution that violate the NAAQS by imposing reasonable control measures on the sources that are within the

jurisdiction of the state while also authorizing EPA to approve such attainment plans and demonstrations even though they do not fully address the public health impacts of international transport. Also, generally, monitoring data influenced by international transport may not be excluded from regulatory determinations. However, depending on the nature and scope of international emissions events affecting air quality in the U.S., the event-influenced data may qualify for exclusion under the Exceptional Events Rule. The EPA encourages affected air agencies to coordinate with their EPA regional office to identify approaches to evaluate the potential impacts of international transport and to determine the most appropriate information and analytical methods for each area's unique situation. The EPA will also work with states that are developing attainment plans for which section 179B is relevant, and ensure the states have the benefit of the EPA's understanding of international transport of ozone and ozone precursors.

The EPA has used section 179B authority previously to approve attainment plans for Mexican border areas in El Paso, TX (O<sub>3</sub>, PM<sub>10</sub>, and CO plans); and Nogales, AZ (PM<sub>10</sub> plan). The 24-hour PM<sub>10</sub> attainment plan for Nogales, AZ, was approved by EPA as sufficient to demonstrate attainment of the NAAQS by the Moderate classification deadline, but for international emissions sources in the Nogales Municipality, Mexico area (77 FR 38400, June 27, 2012).

States are encouraged to consult with their EPA Regional Office to establish appropriate technical requirements for these analyses.

## IX. 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*

*of the Final National Ambient Air Quality Standards for Ground-Level Ozone*, October 2015. 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 three alternative O<sub>3</sub> NAAQS nationwide. Specifically, the RIA examines the alternatives of 65 ppb and 70 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<sub>3</sub> 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 final rule.

### B. Paperwork Reduction Act

The information collection requirements in this final rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). The information collection requirements are not enforceable until OMB approves them. The Information Collection Request (ICR) document prepared by the EPA for these revisions has been assigned EPA ICR #2313.04.

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 extending the length of the required O<sub>3</sub> monitoring season in 32 states and the District of Columbia and the revised O<sub>3</sub> monitoring seasons will become effective on January 1, 2017. We are also revising the PAMS monitoring requirements to reduce the number of required PAMS sites while improving spatial coverage, and requiring states in moderate or above O<sub>3</sub> non-attainment areas and the O<sub>3</sub> transport region to develop an enhanced monitoring plan as part of the PAMS requirements. Monitoring agencies will need to comply with the PAMS requirements by June 1, 2019. In addition, we are revising the O<sub>3</sub> FRM to establish a new, additional technique for measuring O<sub>3</sub> in the ambient air. It will be

incorporated into the existing O<sub>3</sub> FRM, using the same calibration procedure in Appendix D of 40 CFR part 50. We are also making changes to the procedures for testing performance characteristics and determining comparability between candidate FEMs and reference methods.

For the purposes of ICR number 2313.04, the burden figures represent the burden estimate based on the requirements contained in this rule. The burden estimates are for the 3-year period from 2016 through 2018. The implementation of the PAMS changes will occur beyond the time frame of this ICR with implementation occurring in 2019. The cost estimates for the PAMS network (including revisions) will be captured in future routine updates to the Ambient Air Quality Surveillance ICR that are required every 3 years by OMB. The addition of a new FRM in 40 CFR part 50 and revisions to the O<sub>3</sub> 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 changes to the O<sub>3</sub> seasons in this final rule. This information collection is estimated to involve 158 respondents for a total cost of approximately \$24,597,485 (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<sub>3</sub> monitoring network. The labor costs associated with these hours are \$20,209,966. Also included in the total are other costs of operations and maintenance of \$2,254,334 and equipment and contract costs of \$2,133,185. The actual labor cost increase to expand the O<sub>3</sub> monitoring seasons is \$2,064,707. 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 \$2,670,360. 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.

#### C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small

entities. Rather, this rule establishes national standards for allowable concentrations of O<sub>3</sub> 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 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 (UMRA)

This action does not contain an unfunded federal mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The revisions to the O<sub>3</sub> NAAQS impose no enforceable duty on any state, local, or tribal governments or the private sector beyond those duties already established in the CAA. The expected costs associated with the monitoring requirements are described in the EPA's ICR document, and these costs are not expected to exceed \$100 million in the aggregate for any year.

Furthermore, as indicated previously, in setting 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 *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 RIA pursuant to the UMRA would not furnish any information which the court could consider in reviewing the NAAQS]). With regard to the sections of the rule preamble discussing implementation of the revisions to the O<sub>3</sub> NAAQS, the CAA imposes the obligation for states to submit SIPs to implement the NAAQS for O<sub>3</sub>. To the extent the EPA's discussion of implementation topics in this final rule may reflect some interpretations of those requirements, those interpretations do not impose obligations beyond the duties already established in the CAA and thus do not constitute a federal mandate for purposes of UMRA. The EPA is also adopting a grandfathering provision for

certain PSD permits in this action, as described above. However, that provision does not impose any mandate on any state, local, or tribal government or the private sector, but rather provides relief from requirements that would otherwise result from the new standards. In addition, the EPA is not requiring states to revise their SIPs to include such a provision.

#### 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. This rule provides increased protection from adverse effects of ozone for the entire country, including for sensitive populations, and tribes are not obligated to adopt or implement any NAAQS. In addition, tribes are not obligated to conduct ambient monitoring for O<sub>3</sub> or to adopt the ambient monitoring requirements of 40 CFR part 58. Even if this action were determined to have tribal implications within the meaning of Executive Order 13175, it will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law. Thus, consultation under Executive Order 13175 was not required.

Nonetheless, consistent with the "EPA Policy on Consultation and Coordination with Indian Tribes", the EPA offered government-to-government consultation on the proposed rule. No tribe requested government-to-government consultation with the EPA on this rule. In addition, the EPA conducted outreach to tribal environmental professionals, which included participation in the Tribal Air call sponsored by the National Tribal Air Association, and two other calls available to tribal environmental professionals. During the public comment period we received comments on the proposed rule from seven tribes and three tribal organizations.

#### 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 NAAQS for O<sub>3</sub>; 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<sup>256</sup> such as all people with lung disease and people active outdoors, are at increased risk for health effects associated with exposure to O<sub>3</sub> in ambient air. Because children are considered an at-risk lifestage, we have carefully evaluated the environmental health effects of exposure to O<sub>3</sub> 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<sub>3</sub>, 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 is not requiring the use of specific, prescribed analytical methods. Rather, the Agency is allowing the use of any method that meets the prescribed performance criteria. Ambient air concentrations of O<sub>3</sub> are currently measured by the FRM in 40 CFR part 50, Appendix D (Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere) or by FEM that meet the requirements of 40 CFR part 53. Procedures are available in part 53 that allow for the approval of an FEM for O<sub>3</sub> 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 that this action will not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations or indigenous peoples. The action described in this notice is to strengthen the NAAQS for O<sub>3</sub>.

The primary NAAQS are established at a level that is requisite to protect public health, including the health of sensitive or at-risk groups, with an adequate margin of safety. The NAAQS decisions are based on an explicit and comprehensive assessment of the current scientific evidence and associated exposure/risk analyses. More specifically, EPA expressly considers the available information regarding health effects among at-risk populations, including that available for low-income populations and minority populations, in decisions on NAAQS. Where low-income populations or minority populations are among the at-risk populations, the decision on the standard is based on providing protection for these and other at-risk populations and lifestages. Where such populations are not identified as at-risk populations, a NAAQS that is established to provide protection to the at-risk populations would also be expected to provide protection to all

other populations, including low-income populations and minority populations.

The ISA, HREA, and PA for this review, which include identification of populations at risk from O<sub>3</sub> health effects, are available in the docket, EPA–HQ–OAR–2008–0699. The information on at-risk populations for this NAAQS review is summarized and considered earlier in this preamble (see section II.A). This final rule increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority populations, low-income populations or indigenous peoples. This rule establishes uniform national standards for O<sub>3</sub> in ambient air that, in the Administrator’s judgment, protect public health, including the health of sensitive groups, with an adequate margin of safety.

Although it is part of a separate docket (EPA–HQ–OAR–2013–0169) and is not part of the rulemaking record for this action, EPA has prepared a RIA of this decision. As part of the RIA, a demographic analysis was conducted. While, as noted in the RIA, the demographic analysis is not a full quantitative, site-specific exposure and risk assessment, that analysis examined demographic characteristics of persons living in areas with poor air quality relative to the proposed standard. Specifically, Chapter 9, section 9.10 (page 9–7) and Appendix 9A of the RIA describe this proximity and socio-demographic analysis. This analysis found that in areas with poor air quality relative to the revised standard,<sup>257</sup> the representation of minority populations was slightly greater than in the U.S. as a whole. Because the air quality in these areas does not currently meet the revised standard, populations in these areas would be expected to benefit from implementation of the strengthened standard, and, thus, would be more affected by strategies to attain the revised standard. This analysis, which evaluates the potential implications for minority populations and low-income populations of future air pollution control actions that state and local agencies may consider in implementing the revised O<sub>3</sub> NAAQS described in this decision notice are discussed in Appendix 9A of the RIA. 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](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html) and

<sup>256</sup> 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 lifestage.

<sup>257</sup> This refers to monitored areas with O<sub>3</sub> design values above the revised and alternative standards.

in the RIA docket (EPA-HQ-OAR-2013-0169). As noted above, although an RIA has been prepared, the results of the RIA have not been considered in issuing this final rule.

#### K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is a "major rule" as defined by 5 U.S.C. 804(2).

#### References

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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: October 1, 2015.

Gina McCarthy, Administrator.

For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is 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 paragraphs (c)(2)(iii) and (vi) and (c)(3)(i); and

■ b. Removing and reserving paragraphs (c)(2)(iv) and (v) and (c)(3)(ii) and (iii).

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 a new or revised 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 FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA INFLUENCED BY EXCEPTIONAL EVENTS FOR USE IN INITIAL AREA DESIGNATIONS

Exceptional events/regulatory action	Exceptional events deadline schedule <sup>d</sup>
Flagging and initial event description deadline for data years 1, 2 and 3. <sup>a</sup>	If state and tribal initial designation recommendations for a new/revised NAAQS are due August through January, then the flagging and initial event description deadline will be the July 1 prior to the recommendation deadline. If state and tribal recommendations for a new/revised NAAQS are due February through July, then the flagging and initial event description deadline will be the January 1 prior to the recommendation deadline.
Exceptional events demonstration submittal deadline for data years 1, 2 and 3. <sup>a</sup>	No later than the date that state and tribal recommendations are due to EPA.
Flagging, initial event description and exceptional events demonstration submittal deadline for data year 4 <sup>b</sup> and, where applicable, data year 5. <sup>c</sup>	By the last day of the month that is 1 year and 7 months after promulgation of a new/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/revised NAAQS. b. If the EPA notifies the state/tribe that it intends to complete the initial area designations process according to a schedule between 2 and 3 years, the deadline is 5 months prior to the date specified for final designations decisions in such EPA notification.

<sup>a</sup> Where data years 1, 2, and 3 are those years expected to be considered in state and tribal recommendations.  
<sup>b</sup> Where data year 4 is the additional year of data that the EPA may consider when it makes final area designations for a new/revised NAAQS under the standard designations schedule.  
<sup>c</sup> Where data year 5 is the additional year of data that the EPA may consider when it makes final area designations for a new/revised NAAQS under an extended designations schedule.  
<sup>d</sup> 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 as specified in 40 CFR 58.15(a)(2). 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 first 8 months of the calendar year. Data flagging, initial event description and exceptional events 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<sub>3</sub>) is 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<sub>3</sub> 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<sub>3</sub> concentration is less than or equal to 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<sub>3</sub> is 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<sub>3</sub> 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<sub>3</sub> concentration is less than or equal to 0.070 ppm, as determined in accordance with appendix U to this part.

■ 4. Revise appendix D to part 50 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<sub>3</sub>) in ambient air for determining compliance with the national primary and secondary ambient air quality standards for O<sub>3</sub> as specified in 40 CFR part 50. This automated method is applicable to the measurement of ambient O<sub>3</sub> 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<sub>3</sub> in sampled air with either ethylene (C<sub>2</sub>H<sub>4</sub>) or nitric oxide (NO) gas. An ambient air sample stream and a specific flowing concentration of either C<sub>2</sub>H<sub>4</sub> (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<sub>3</sub> 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<sub>3</sub> (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 wavelength specificity for O<sub>3</sub>; a pump, flow control, and sample conditioning system for sampling the ambient air and moving it into and through the measurement cell; a sample air dryer as necessary to meet the water vapor interference limit requirement specified in subpart B of part 53 of this chapter; a means to supply, meter, and mix a constant, flowing stream of either C<sub>2</sub>H<sub>4</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> in the O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> concentrations in a dynamic flow system. The concentration of O<sub>3</sub> 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 ( $\alpha$ ) of O<sub>3</sub> 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<sub>3</sub> 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,

$$\text{Transmittance} = \frac{I}{I_0} = e^{-\alpha cl} \quad (1)$$

Where:

$\alpha$  = absorption coefficient of O<sub>3</sub> at 254 nm = 308 ± 4 atm<sup>-1</sup> cm<sup>-1</sup> at 0 °C and 760 torr,<sup>1, 2, 3, 4, 5, 6, 7</sup>

$c$  = O<sub>3</sub> concentration in atmospheres, and  
 $l$  = optical path length in cm.

A stable O<sub>3</sub> generator is used to produce O<sub>3</sub> concentrations over the required calibration

concentration range. Each O<sub>3</sub> 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,

$$c(\text{atm}) = -\frac{1}{\alpha l} \left( \ln \frac{I}{I_0} \right) \quad (2a)$$

or

$$c(\text{ppm}) = -\frac{10^6}{\alpha l} \left( \ln \frac{I}{I_0} \right). \quad (2b)$$

The calculated O<sub>3</sub> concentrations must be corrected for O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub>, the transfer standard may replace the O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> concentration.

**4.3.6 Temperature indicator.** A device to indicate temperature must be used that is accurate to  $\pm 1$  °C.

**4.3.7 Barometer or pressure indicator.** A device to indicate barometric pressure must be used that is accurate to  $\pm 2$  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<sub>3</sub> analyzer, and it must be free of NO, C<sub>2</sub>H<sub>4</sub>, and other species which react with O<sub>3</sub>. 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<sub>0</sub> reference measurement must be derived from the same source as the zero air used for generation of the O<sub>3</sub> concentration to be assayed (I measurement). When using the photometer to certify a transfer standard

having its own source of O<sub>3</sub>, 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<sub>3</sub> 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

$$E = \frac{A_1 - A_2/R}{A_1} \times 100\% \quad (3)$$

Where:

E = linearity error, percent

A<sub>1</sub> = assay of the original concentration

A<sub>2</sub> = 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> concentrations.** The operator must carry out the following steps to properly assay O<sub>3</sub> 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<sub>3</sub> generator to produce an O<sub>3</sub> 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<sub>0</sub>.

4.5.3.8 Actuate the two-way valve to allow the photometer to sample the O<sub>3</sub> 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<sub>3</sub> concentration from equation 4. An average of several determinations will provide better precision.

$$[O_3]_{OUT} = \left(\frac{-1}{\alpha l}\right) \ln \left(\frac{I}{I_0}\right) \left(\frac{T}{273}\right) \left(\frac{760}{P}\right) \times \frac{10^6}{L} \quad (4)$$

Where:

[O<sub>3</sub>]<sub>OUT</sub> = O<sub>3</sub> concentration, ppm

α = absorption coefficient of O<sub>3</sub> at 254 nm = 308 atm<sup>-1</sup> cm<sup>-1</sup> at 0° C and 760 torr

l = optical path length, cm

T = sample temperature, K

P = sample pressure, torr

L = correction factor for O<sub>3</sub> losses from

4.5.2.5 = (1 - fraction of O<sub>3</sub> 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<sub>3</sub> levels. See the photometer instruction manual and Reference 13 for guidance.

4.5.3.11 Obtain additional O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> analyzer and the photometer or transfer standard to warm-up and stabilize.

4.5.5.2 Allow the O<sub>3</sub> analyzer to sample zero air until a stable response is obtained and then adjust the O<sub>3</sub> 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<sub>3</sub> concentration standard of approximately 80% of the desired upper range limit (URL) of the O<sub>3</sub> analyzer. Allow the O<sub>3</sub> analyzer to sample this O<sub>3</sub> concentration standard until a stable response is obtained.

4.5.5.4 Adjust the O<sub>3</sub> analyzer's span control to obtain the desired response equivalent to the calculated standard concentration. Record the O<sub>3</sub> 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<sub>3</sub> concentration standards (a minimum of 5 are recommended) over the calibration scale of the O<sub>3</sub> analyzer by adjusting the O<sub>3</sub> source or by Option 1. For each O<sub>3</sub> concentration standard, record the O<sub>3</sub> concentration and the corresponding analyzer response.

4.5.5.6 Plot the O<sub>3</sub> analyzer responses (vertical or Y-axis) versus the corresponding O<sub>3</sub> 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<sub>3</sub> concentrations required in steps 4.5.3.11 and 4.5.5.5 may be obtained by dilution of the O<sub>3</sub> 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<sub>3</sub> generator. A mixing chamber between the O<sub>3</sub> generator and the output manifold is also required. The flow rate through the O<sub>3</sub> generator (F<sub>O</sub>) and the dilution air flow rate (F<sub>D</sub>) are measured with a flow or volume standard that is traceable to a NIST flow or volume calibration standard. Each O<sub>3</sub> 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<sub>3</sub>]'<sub>OUT</sub> = diluted O<sub>3</sub> concentration, ppm

F<sub>O</sub> = flow rate through the O<sub>3</sub> generator, liter/min

F<sub>D</sub> = 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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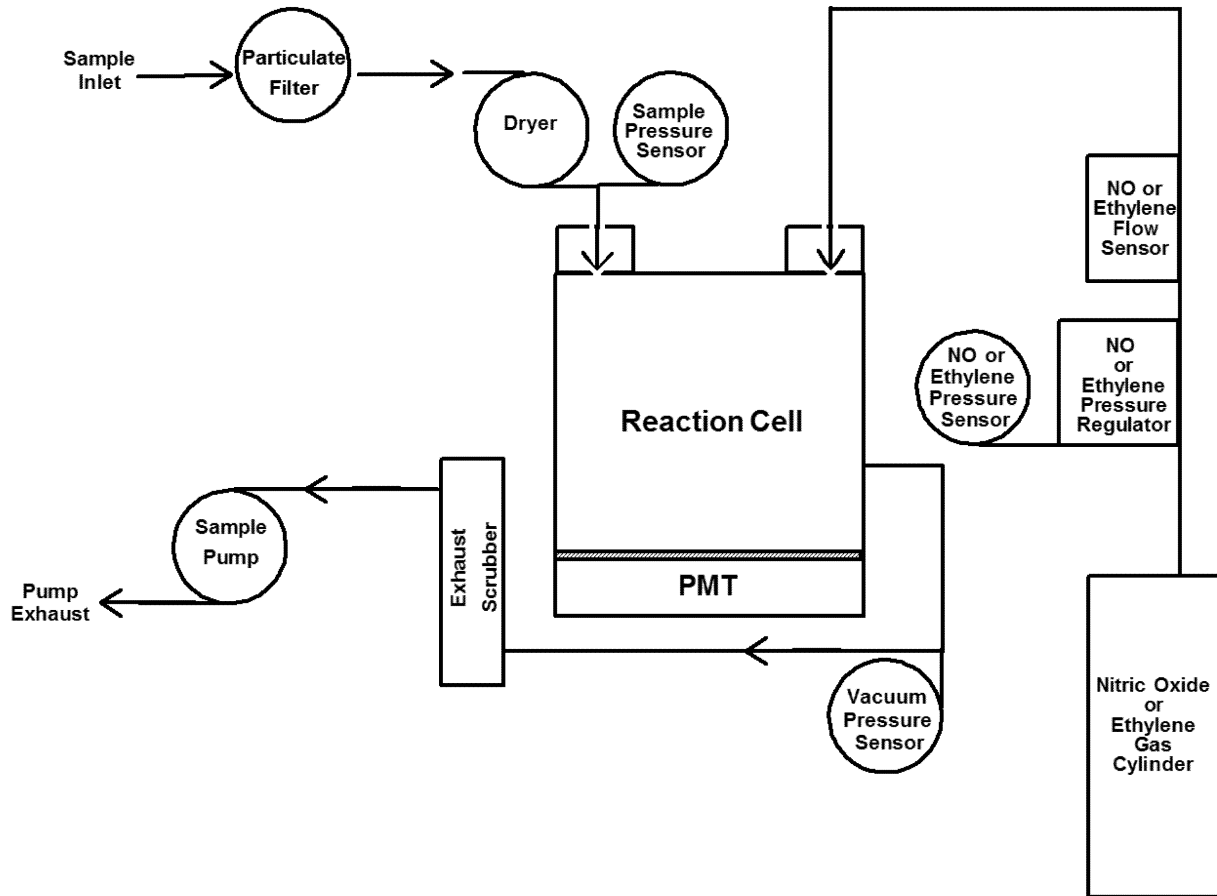


Figure 1. Gas-phase chemiluminescence analyzer schematic diagram, where PMT means photomultiplier tube.

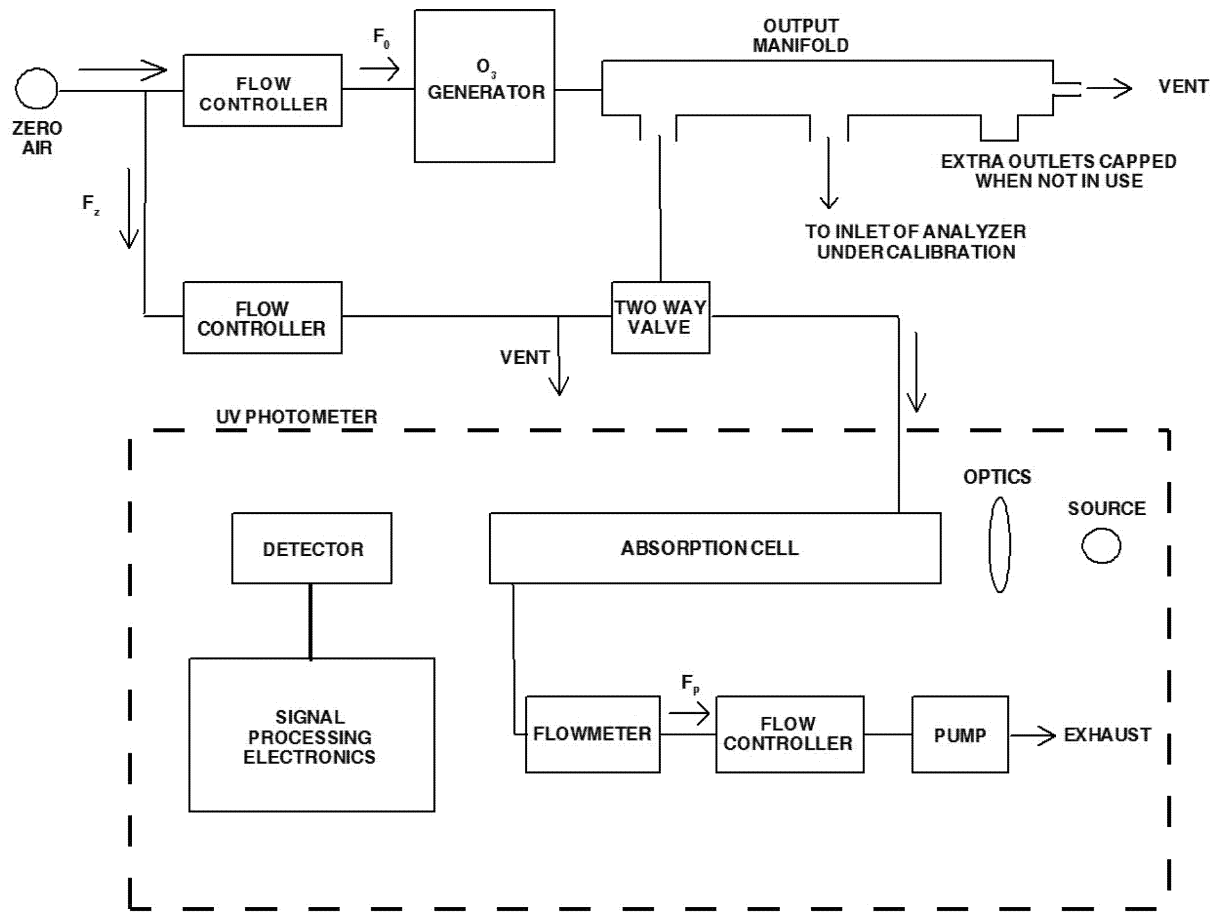


Figure 2. Schematic diagram of a typical UV photometric calibration system.

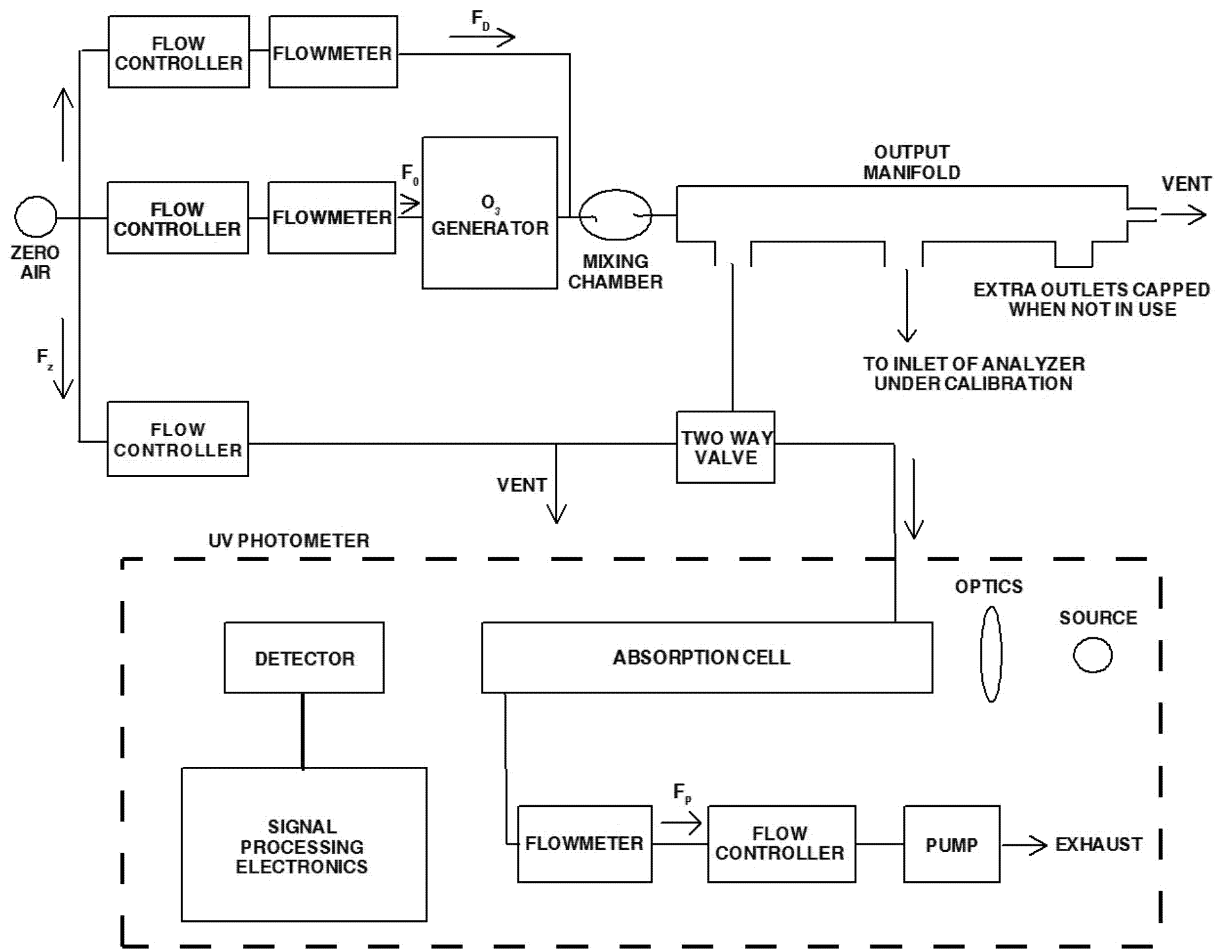


Figure 3. Schematic diagram of a typical UV photometric calibration system (Option 1).

■ 5. Add appendix U to Part 50 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<sub>3</sub>) specified in § 50.19 are met at an ambient O<sub>3</sub> air quality monitoring site. Data reporting, data handling, and computation procedures to be used in making comparisons between reported O<sub>3</sub> concentrations and the levels of the O<sub>3</sub> 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<sub>3</sub> 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 year.

*Collocated monitors* refers to the instance of two or more O<sub>3</sub> monitors operating at the same physical location.

*Daily maximum 8-hour average O<sub>3</sub> 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<sub>3</sub> 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<sub>3</sub> concentrations.

*O<sub>3</sub> monitoring season* refers to the span of time within a year when individual states are required to measure ambient O<sub>3</sub> concentrations, as listed in Appendix D to part 58 of this chapter.

*Site* refers to an ambient O<sub>3</sub> air quality monitoring site.

*Site data record* refers to the set of hourly O<sub>3</sub> 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<sub>3</sub> 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.

(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 shall designate one monitor as the primary monitor for the site.

(ii) Hourly O<sub>3</sub> concentration data from a secondary monitor shall be substituted into

the site data record whenever a valid hourly O<sub>3</sub> concentration is not obtained from the primary monitor. In the event that hourly O<sub>3</sub> concentration data are available for more than one secondary monitor, the hourly concentration values from the secondary 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<sub>3</sub> 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<sub>3</sub> 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, respectively, 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, or equivalently, if the sum of the available hourly concentrations is greater than 0.567 ppm. 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<sub>3</sub> 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<sub>3</sub> 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. the following day (i.e., the 8-hour averages for 7:00 a.m. to 11:00 p.m.). Daily maximum 8-hour average O<sub>3</sub> concentrations shall be determined for each day with ambient O<sub>3</sub> monitoring data, including days outside the O<sub>3</sub> monitoring season if those data are available.

(d) A daily maximum 8-hour average O<sub>3</sub> 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<sub>3</sub> concentration shall also be considered valid if it is greater than the level of the NAAQS. Hourly O<sub>3</sub> 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<sub>3</sub> design value statistic is the annual fourth-highest daily maximum 8-hour O<sub>3</sub> concentration, averaged over three years, expressed in ppm. The fourth-highest daily maximum 8-hour O<sub>3</sub> 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<sub>3</sub> monitoring data. Design values shall be reported in ppm 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<sub>3</sub> 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<sub>3</sub> concentration (i.e., the design value) is less than or equal to 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<sub>3</sub> concentrations are available for at least 90% of the days within the O<sub>3</sub> monitoring season, on average, for the 3-year period, with a minimum of at least 75% of the days within the O<sub>3</sub> 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<sub>3</sub> NAAQS are demonstrated by examples 1 and 2 as follows:

**EXAMPLE 1—SITE MEETING THE PRIMARY AND SECONDARY O<sub>3</sub> NAAQS**

Year	Percent valid days within O <sub>3</sub> monitoring season (Data completeness)	1st highest daily max 8-hour O <sub>3</sub> (ppm)	2nd highest daily max 8-hour O <sub>3</sub> (ppm)	3rd highest daily max 8-hour O <sub>3</sub> (ppm)	4th highest daily max 8-hour O <sub>3</sub> (ppm)	5th highest daily max 8-hour O <sub>3</sub> (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<sub>3</sub> NAAQS because the 3-year average of the annual fourth-highest daily maximum 8-hour average O<sub>3</sub> concentrations (i.e., 0.065666 ppm, truncated

to 0.065 ppm) is less than or equal to 0.070 ppm. The minimum data completeness requirements are also met (i.e., design value is considered valid) because the average percent of days within the O<sub>3</sub> 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 O<sub>3</sub> NAAQS**

Year	Percent valid days within O <sub>3</sub> monitoring season (Data completeness)	1st highest daily max 8-hour O <sub>3</sub> (ppm)	2nd highest daily max 8-hour O <sub>3</sub> (ppm)	3rd highest daily max 8-hour O <sub>3</sub> (ppm)	4th highest daily max 8-hour O <sub>3</sub> (ppm)	5th highest daily max 8-hour O <sub>3</sub> (ppm)
2014 .....	96	0.085	0.080	0.079	0.074	0.072



EXAMPLE 2—SITE FAILING TO MEET THE PRIMARY AND SECONDARY O<sub>3</sub> NAAQS—Continued

Year	Percent valid days within O <sub>3</sub> monitoring season (Data completeness)	1st highest daily max 8-hour O <sub>3</sub> (ppm)	2nd highest daily max 8-hour O <sub>3</sub> (ppm)	3rd highest daily max 8-hour O <sub>3</sub> (ppm)	4th highest daily max 8-hour O <sub>3</sub> (ppm)	5th highest daily max 8-hour O <sub>3</sub> (ppm)
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<sub>3</sub> NAAQS because the 3-year average of the annual fourth-highest daily maximum 8-hour average O<sub>3</sub> concentrations (*i.e.*, 0.073333 ppm, truncated to 0.073 ppm) is greater than 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% (*i.e.*, design value would not otherwise be considered valid).

**PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION 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**

■ 8. 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 permit application for a stationary source or modification with respect to the revised national ambient air quality standards for ozone published on October 26, 2015 if:

(i) The reviewing authority has determined the permit application subject to this section to be complete on or before October 1, 2015. 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 December 28, 2015 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 permit application for a stationary source or modification with respect to the revised national ambient air quality standards for ozone published on October 26, 2015 if:

(i) The Administrator has determined the permit application subject to this section to be complete on or before October 1, 2015. 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 December 28, 2015 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 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<sub>2</sub>, CO, O<sub>3</sub>, and NO<sub>2</sub>**

■ 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.<sup>258</sup>

\* \* \* \* \*

■ 14. Revise Table B–1 to Subpart B of Part 53 to read as follows:

<sup>258</sup>NO<sub>2</sub> 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

Performance parameter	Units <sup>1</sup>	SO <sub>2</sub>		O <sub>3</sub>		CO		NO <sub>2</sub> (Std. range)	Definitions and test procedures
		Std. range <sup>3</sup>	Lower range <sup>2,3</sup>	Std. range <sup>3</sup>	Lower range <sup>2,3</sup>	Std. range <sup>3</sup>	Lower range <sup>2,3</sup>		
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	0.0025	0.001	0.2	0.1	0.005	Sec. 53.23(b)
3. Lower detectable limit .....	ppm .....	0.002	0.001	0.005	0.002	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	Percent .....	—	—	—	—	—	—	±20.0	Sec. 53.23(e)
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.	Percent <sup>5</sup> ....	—	—	—	—	—	—	—	Sec. 53.23(e)
80% of upper range limit.	Percent <sup>5</sup> ....	2	2	2	2	1.0	1.0	4	Sec. 53.23(e)
		—	—	—	—	—	—	—	Sec. 53.23(e)
		2	2	2	2	1.0	1.0	6	Sec. 53.23(e)

<sup>1</sup>To convert from parts per million (ppm) to µg/m<sup>3</sup> 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.

<sup>2</sup>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.

<sup>3</sup>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.

<sup>4</sup>For nitric oxide interference for the SO<sub>2</sub> UVF method, interference equivalent is ±0.0003 ppm for the lower range.

<sup>5</sup>Standard deviation expressed as percent of the URL.

Table B-3 to Subpart B of Part 53—Interferent Test Concentration,<sup>1</sup> 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 <sub>2</sub>	Ultraviolet fluorescence			<sup>5</sup> 0.1	<sup>4</sup> 0.14	0.5	0.5			0.5	0.2	20,000				0.05
SO <sub>2</sub>	Flame photometric			0.01	<sup>4</sup> 0.14			750				<sup>3</sup> 20,000	50			
SO <sub>2</sub>	Gas chromatography			0.1	<sup>4</sup> 0.14			750				<sup>3</sup> 20,000	50			
SO <sub>2</sub>	Spectrophotometric-wet chemical (pararosaniline)	0.2	0.1	0.1	<sup>4</sup> 0.14	0.5		750		0.5						
SO <sub>2</sub>	Electrochemical	0.2	0.1	0.1	<sup>4</sup> 0.14	0.5	0.5		0.2	0.5		<sup>3</sup> 20,000				
SO <sub>2</sub>	Conductivity	0.2	0.1		<sup>4</sup> 0.14	0.5		750								
SO <sub>2</sub>	Spectrophotometric-gas phase, including DOAS				<sup>4</sup> 0.14	0.5				0.5	0.2					
O <sub>3</sub>	Ethylene chemiluminescence			0.1				750		<sup>4</sup> 0.08		20,000				
O <sub>3</sub>	NO-chemiluminescence			0.1		0.5		750		<sup>4</sup> 0.08		20,000				
O <sub>3</sub>	Electrochemical		<sup>3</sup> 0.1		0.5	0.5				<sup>4</sup> 0.08						
O <sub>3</sub>	Spectrophotometric-wet chemical (potassium iodide)		<sup>3</sup> 0.1		0.5	0.5	0.5			<sup>4</sup> 0.08						

O <sub>3</sub>	Spectrophotometric -gas phase, including ultraviolet absorption and DOAS				0.5	0.5	0.5			<sup>4</sup> 0.08	0.02	20,000				
CO	Non-dispersive Infrared							750				20,000	<sup>4</sup> 10			
CO	Gas chromatography with flame ionization detector											20,000	<sup>4</sup> 10		0.5	
CO	Electrochemical						0.5		0.2			20,000	<sup>4</sup> 10			
CO	Catalytic combustion-thermal detection		0.1					750	0.2			20,000	<sup>4</sup> 10	5.0	0.5	
CO	IR fluorescence							750				20,000	<sup>4</sup> 10		0.5	
CO	Mercury replacement-UV photometric								0.2				<sup>4</sup> 10		0.5	
NO <sub>2</sub>	Chemiluminescent		<sup>3</sup> 0.1		0.5	<sup>4</sup> 0.1	0.5					20,000				
NO <sub>2</sub>	Spectrophotometric -wet chemical (azo-dye reaction)				0.5	<sup>4</sup> 0.1	0.5	750		0.5						
NO <sub>2</sub>	Electrochemical	0.2	<sup>3</sup> 0.1		0.5	<sup>4</sup> 0.1	0.5	750		0.5		20,000	50			
NO <sub>2</sub>	Spectrophotometric -gas phase		<sup>3</sup> 0.1		0.5	<sup>4</sup> 0.1	0.5			0.5		20,000	50			

1. Concentrations of interferents listed must be prepared and controlled to  $\pm 10$  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  $\pm 10$  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.

**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	$S_n = \frac{1}{6} \sum_{i=7}^{12} P_i$															
		$SD_n = \frac{S_n - S_{n-1}}{S_{n-1}} \times 100\%$															
		$SD_n = \frac{S_n - S'_{n-1}}{S'_{n-1}} \times 100\%$															
PRECISION	20% URL ( $P_{20}$ )	$P_{20} = \% \text{ STANDARD DEVIATION OF } (P_1...P_6)$															
	80% URL ( $P_{80}$ )	$P_{80} = \% \text{ STANDARD DEVIATION OF } (P_7...P_{12})$															

Figure B-5. Form for calculating zero drift, span drift, and precision (§ 53.23(e)).

\* \* \* \* \*

**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<sub>2</sub>, CO, O<sub>3</sub>, and NO<sub>2</sub>.**

\* \* \* \* \*

(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)(9) through (11) to read as follows:

**§ 58.10 Annual monitoring network plan and periodic network assessment.**

(a) \* \* \*

(9) The annual monitoring network plan shall provide for the required O<sub>3</sub> sites to be operating on the first day of the applicable required O<sub>3</sub> monitoring season in effect on January 1, 2017 as listed in Table D–3 of appendix D of this part.

(10) A plan for making Photochemical Assessment Monitoring Stations (PAMS) measurements, if applicable, in accordance with the requirements of appendix D paragraph 5(a) of this part shall be submitted to the EPA Regional Administrator no later than July 1, 2018. The plan shall provide for the required

PAMS measurements to begin by June 1, 2019.

(11) An Enhanced Monitoring Plan for O<sub>3</sub>, if applicable, in accordance with the requirements of appendix D paragraph 5(h) of this part shall be submitted to the EPA Regional Administrator no later than October 1, 2019 or two years following the effective date of a designation to a classification of Moderate or above O<sub>3</sub> nonattainment, whichever is later.

\* \* \* \* \*

■ 21. Section § 58.11 is amended by revising paragraph (c) to read as follows:

**§ 58.11 Network technical requirements.**

\* \* \* \* \*

(c) State and local governments must follow the network design criteria contained in appendix D to this part in designing and maintaining the SLAMS stations. The final network design and all changes in design are subject to approval of the Regional Administrator. NCore and STN network design and changes are also subject to approval of the Administrator. Changes in SPM stations do not require approvals, but a change in the designation of a monitoring site from SLAMS to SPM requires approval of the Regional Administrator.

\* \* \* \* \*

■ 22. Amend § 58.13 by adding paragraphs (g) and (h) to read as follows:

**§ 58.13 Monitoring network completion.**

\* \* \* \* \*

(g) The O<sub>3</sub> monitors required under appendix D, section 4.1 of this part must operate on the first day of the applicable required O<sub>3</sub> 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, 2019.

**Subpart F—Air Quality Index Reporting**

■ 23. 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**

■ 24. 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 \* \* \**

(i) Ozone monitoring is required at SLAMS monitoring sites only during the seasons of the year that are conducive to O<sub>3</sub> formation (*i.e.*, “ozone season”) as described below in Table D–3 of this appendix. These O<sub>3</sub> seasons are also identified in the AQS files on a state-by-state basis. Deviations from the O<sub>3</sub> 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<sub>3</sub> NAAQS exceedances, as well as occurrences of the Moderate air quality index level, regional consistency, and logistical issues such as site access. 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<sub>3</sub> monitoring season requirements in Table D–3 revoke all previously approved Regional Administrator waivers. Requests for monitoring season deviations must be accompanied by relevant supporting information. Information on how to analyze O<sub>3</sub> data to support a change to the O<sub>3</sub> season in support of the 8-hour standard for the entire network in a specific state can be found in reference 8 to this appendix. Ozone monitors at NCore stations are required to be operated year-round (January to December).

TABLE D–3<sup>1</sup> 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.



TABLE D-3<sup>1</sup> TO APPENDIX D OF PART 58. OZONE MONITORING SEASON BY STATE—Continued

State	Begin Month	End Month
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.
Virgin Islands	January	December.

<sup>1</sup> The required O<sub>3</sub> 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 PAMS measurements at each NCore site required under paragraph 3(a) of this appendix located in a CBSA with a population of 1,000,000 or more, based on the latest available census figures.

(b) PAMS measurements include:

- (1) Hourly averaged speciated volatile organic compounds (VOCs);
- (2) Three 8-hour averaged carbonyl samples per day on a 1 in 3 day schedule, or hourly averaged formaldehyde;
- (3) Hourly averaged O<sub>3</sub>;

(4) Hourly averaged nitrogen oxide (NO), true nitrogen dioxide (NO<sub>2</sub>), and total reactive nitrogen (NO<sub>x</sub>);

- (5) Hourly averaged ambient temperature;
- (6) Hourly vector-averaged wind direction;
- (7) Hourly vector-averaged wind speed;
- (8) Hourly average atmospheric pressure;
- (9) Hourly averaged relative humidity;
- (10) Hourly precipitation;
- (11) Hourly averaged mixing-height;
- (12) Hourly averaged solar radiation; and
- (13) Hourly averaged ultraviolet radiation.

(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<sub>3</sub> precursors.

The alternative location can be outside of the CBSA or outside of the monitoring agencies jurisdiction. In cases where the alternative location crosses jurisdictions the waiver will be contingent on the monitoring agency responsible for the alternative location including the required PAMS measurements in their annual monitoring plan required under § 58.10 and continued successful collection of PAMS measurements at the alternative location. This waiver can be revoked in cases where the Regional Administrator determines the PAMS measurements are not being collected at the alternate location in compliance with paragraph (b) of this section.

(d) The EPA Regional Administrator may grant a waiver to allow speciated VOC measurements to be made as three 8-hour averages on every third day during the PAMS

season as an alternative to 1-hour average speciated VOC measurements in cases where the primary VOC compounds are not well measured using continuous technology due to low detectability of the primary VOC compounds or for logistical and other programmatic constraints.

(e) The EPA Regional Administrator may grant a waiver to allow representative meteorological data from nearby monitoring stations to be used to meet the meteorological requirements in paragraph 5(b) where the monitoring agency can demonstrate the data is collected in a manner consistent with EPA quality assurance requirements for these measurements.

(f) The EPA Regional Administrator may grant a waiver from the requirement to collect PAMS measurements in locations where CBSA-wide O<sub>3</sub> design values are equal to or less than 85% of the 8-hour O<sub>3</sub> NAAQS and where the location is not considered by the Regional Administrator to be an important upwind or downwind location for other O<sub>3</sub> nonattainment areas.

(g) At a minimum, the monitoring agency shall collect the required PAMS measurements during the months of June, July, and August.

(h) States with Moderate and above 8-hour O<sub>3</sub> nonattainment areas and states in the Ozone Transport Region as defined in 40 CFR 51.900 shall develop and implement an Enhanced Monitoring Plan (EMP) detailing enhanced O<sub>3</sub> and O<sub>3</sub> precursor monitoring activities to be performed. The EMP shall be submitted to the EPA Regional Administrator no later than October 1, 2019 or two years following the effective date of a designation to a classification of Moderate or above O<sub>3</sub> nonattainment, whichever is later. At a minimum, the EMP shall be reassessed and approved as part of the 5-year network assessments required under 40 CFR 58.10(d). The EMP will include monitoring activities deemed important to understanding the O<sub>3</sub> problems in the state. Such activities may include, but are not limited to, the following:

(1) Additional O<sub>3</sub> monitors beyond the minimally required under paragraph 4.1 of this appendix,

(2) Additional NO<sub>x</sub> or NO<sub>y</sub> 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(g) 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.

\* \* \* \* \*

■ 25. Appendix G of Part 58 is amended by revising table 2 to read as follows:

**Appendix G to Part 58—Uniform Air Quality Index (AQI) and Daily Reporting**

\* \* \* \* \*

TABLE 2—BREAKPOINTS FOR THE AQI

These breakpoints							Equal these AQI's	
O <sub>3</sub> (ppm) 8-hour	O <sub>3</sub> (ppm) 1-hour <sup>1</sup>	PM <sub>2.5</sub> (µg/m <sup>3</sup> ) 24-hour	PM <sub>10</sub> (µg/m <sup>3</sup> ) 24-hour	CO (ppm) 8-hour	SO <sub>2</sub> (ppb) 1-hour	NO <sub>2</sub> (ppb) 1-hour	AQI	Category
0.000–0.054	—	0.0–12.0	0–54	0.0–4.4	0–35	0–53	0–50	Good.
0.055–0.070	—	12.1–35.4	55–154	4.5–9.4	36–75	54–100	51–100	Moderate.
0.071–0.085	0.125–0.164	35.5–55.4	155–254	9.5–12.4	76–185	101–360	101–150	Unhealthy for Sensitive Groups.
0.086–0.105	0.165–0.204	<sup>3</sup> 55.5–150.4	255–354	12.5–15.4	<sup>4</sup> 186–304	361–649	151–200	Unhealthy.
0.106–0.200	0.205–0.404	<sup>3</sup> 150.5–250.4	355–424	15.5–30.4	<sup>4</sup> 305–604	650–1249	201–300	Very Unhealthy.
0.201– <sup>(2)</sup>	0.405–0.504	<sup>3</sup> 250.5–350.4	425–504	30.5–40.4	<sup>4</sup> 605–804	1250–1649	301–400	Hazardous.
<sup>(2)</sup>	0.505–0.604	<sup>3</sup> 350.5–500.4	505–604	40.5–50.4	<sup>4</sup> 805–1004	1650–2049	401–500	

<sup>1</sup> Areas are generally required to report the AQI based on 8-hour ozone values. However, there are a small number of areas where an AQI based on 1-hour ozone values would be more precautionary. In these cases, in addition to calculating the 8-hour ozone index value, the 1-hour ozone index value may be calculated, and the maximum of the two values reported.

<sup>2</sup> 8-hour O<sub>3</sub> values do not define higher AQI values (>301). AQI values > 301 are calculated with 1-hour O<sub>3</sub> concentrations.

<sup>3</sup> If a different SHL for PM<sub>2.5</sub> is promulgated, these numbers will change accordingly.

<sup>4</sup> 1-hr SO<sub>2</sub> values do not define higher AQI values (≥200). AQI values of 200 or greater are calculated with 24-hour SO<sub>2</sub> concentration.



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Part III

## Environmental Protection Agency

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40 CFR Part 63

NESHAP for Brick and Structural Clay Products Manufacturing; and  
NESHAP for Clay Ceramics Manufacturing; Final Rule

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 63**

[EPA-HQ-OAR-2013-0290 and EPA-HQ-OAR-2013-0291; FRL-9933-13-OAR]

RIN 2060-AP69

**NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is finalizing national emission standards for hazardous air pollutants (NESHAP) for Brick and Structural Clay Products (BSCP) Manufacturing and NESHAP for Clay Ceramics Manufacturing. All major sources in these categories must meet maximum achievable control technology (MACT) standards for mercury (Hg), non-mercury (non-Hg) metal hazardous air pollutants (HAP) (or particulate matter (PM) surrogate) and dioxins/furans (Clay Ceramics only); health-based standards for acid gas HAP; and work practice standards, where applicable. The final rule, which has been informed by input from industry (including small businesses), environmental groups, and other stakeholders, protects air quality and promotes public health by reducing emissions of HAP listed in section 112 of the Clean Air Act (CAA).

**DATES:** This action is effective on December 28, 2015. The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of December 28, 2015.

**ADDRESSES:** The EPA has established dockets for this rulemaking under Docket ID No. EPA-HQ-OAR-2013-0291 for BSCP Manufacturing and Docket ID No. EPA-HQ-OAR-2013-0290 for Clay Ceramics Manufacturing. All documents in the dockets are listed in the *regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., confidential business information (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. Publicly available docket materials are available either electronically in *regulations.gov* or in hard copy at the EPA Docket Center, 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 EPA Docket Center is (202) 566-1742.

**FOR FURTHER INFORMATION CONTACT:** For questions about the final rule for BSCP Manufacturing and Clay Ceramics Manufacturing, contact Ms. Sharon Nizich, Minerals and Manufacturing Group, Sector Policies and Program Division (D243-04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; Telephone number: (919) 541-2825; Fax number: (919) 541-5450; Email address: *nizich.sharon@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

*Preamble Acronyms and Abbreviations.* This preamble includes several acronyms and terms used to describe industrial processes, data inventories and risk modeling. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ACI activated carbon injection  
 AEGL Acute Exposure Guideline Level  
 AERMOD air dispersion model used by the HEM-3 model  
 APCD air pollution control device  
 ASOS Automated Surface Observing Systems  
 ATSDR Agency for Toxic Substances and Disease Registry  
 BIA Brick Industry Association  
 BLD bag leak detection  
 BSCP Brick and Structural Clay Products  
 CAA Clean Air Act  
 CalEPA California Environmental Protection Agency  
 CASRN Chemical Abstract Services Registry Number  
 CBI Confidential Business Information  
 CDX Central Data Exchange  
 CEDRI Compliance and Emissions Data Reporting Interface  
 CFR Code of Federal Regulations  
 Cl<sub>2</sub> chlorine  
 CO carbon monoxide  
 CO<sub>2</sub> carbon dioxide  
 CPMS continuous parameter monitoring system  
 CRA Congressional Review Act  
 DHHS Department of Health and Human Services  
 DIFF dry lime injection fabric filter  
 DLA dry limestone adsorber  
 DLS/FF dry lime scrubber/fabric filter  
 DOD Department of Defense  
 ECHO Enforcement and Compliance History Online  
 EPA Environmental Protection Agency  
 ERPG Emergency Response Planning Guideline  
 ERT Electronic Reporting Tool  
 °F degrees Fahrenheit  
 FAA Federal Aviation Administration

FF fabric filter  
 FQPA Food Quality Protection Act  
 FRFA final regulatory flexibility analysis  
 FTIR Fourier transform infrared  
 gr/dscf grains per dry standard cubic foot  
 HAP hazardous air pollutant  
 HBEL health-based emission limit  
 HCl hydrogen chloride  
 HEM-3 Human Exposure Model (Community and Sector version 1.3.1)  
 HF hydrogen fluoride  
 Hg mercury  
 HI hazard index  
 HQ hazard quotient  
 IARC International Agency for Research on Cancer  
 ICR information collection request  
 IRFA initial regulatory flexibility analysis  
 IRIS Integrated Risk Information System  
 lb/hr pounds per hour  
 lb/ton pounds per ton  
 LML lowest measured level  
 LOAEL lowest observed adverse effects level  
 LOEL lowest observed effects level  
 MACT maximum achievable control technology  
 mg/m<sup>3</sup> milligrams per cubic meter  
 MMBtu/yr million British thermal units per year  
 MRL Minimal Risk Level  
 NAAQS National Ambient Air Quality Standards  
 NAICS North American Industry Classification System  
 NAS National Academy of Sciences  
 NATA National Air Toxics Assessment  
 NEI National Emissions Inventory  
 NESHAP national emissions standards for hazardous air pollutants  
 ng/kg nanograms per kilogram  
 NIOSH National Institute for Occupational Safety and Health  
 No. number  
 NO<sub>2</sub> nitrogen dioxide  
 NOAEL no observed adverse effect level  
 Non-Hg non-mercury  
 NO<sub>x</sub> nitrogen oxides  
 NTTAA National Technology Transfer and Advancement Act  
 NWS National Weather Service  
 O<sub>2</sub> oxygen  
 OECD Organisation for Economic Co-operation and Development  
 OEHA Office of Environmental Health Hazard Assessment  
 OM&M operation, maintenance and monitoring  
 OMB Office of Management and Budget  
 %R percent recovery  
 PM particulate matter  
 PM<sub>2.5</sub> particulate matter with particles less than 2.5 micrometers in diameter  
 ppm parts per million  
 PRA Paperwork Reduction Act  
 REL reference exposure level  
 RFA Regulatory Flexibility Act  
 RfC reference concentration  
 RfD reference dose  
 RIA Regulatory Impact Analysis  
 RTR residual risk and technology review  
 SAB Science Advisory Board  
 SBA Small Business Administration  
 SBAR Small Business Advocacy Review  
 SBE Standard Brick Equivalent  
 SBREFA Small Business Regulatory Enforcement Fairness Act

SO<sub>2</sub> sulfur dioxide  
 SSM startup, shutdown and malfunction  
 TEQ 2,3,7,8-tetrachlorodibenzo-p-dioxin  
 toxic equivalents  
 TOSHI target-organ-specific hazard index  
 tph tons per hour  
 tpy tons per year  
 TTN Technology Transfer Network  
 µg/dscm micrograms per dry standard cubic  
 meter  
 µg/m<sup>3</sup> micrograms per cubic meter  
 UMRA Unfunded Mandates Reform Act  
 UPL Upper Prediction Limit  
 VE visible emissions  
 yr year

#### *Background Information Documents.*

On December 18, 2014, the EPA proposed NESHAP for BSCP Manufacturing and NESHAP for Clay Ceramics Manufacturing (79 FR 75622). In this action, we are finalizing the rules. Documents summarizing the public comments on the proposal and presenting the EPA responses to those comments are available in Docket ID No. EPA-HQ-OAR-2013-0291 for BSCP Manufacturing and Docket ID No. EPA-HQ-OAR-2013-0290 for Clay Ceramics Manufacturing.

*Organization of This Document.* The information in this preamble is organized as follows:

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  - G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
  - H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use
  - I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR part 51
  - J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
  - K. Congressional Review Act (CRA)

### **I. General Information**

#### *A. Executive Summary*

##### **1. Purpose of the Regulatory Action**

Section 112(d) of the CAA requires the EPA to set emissions standards for HAP emitted by sources in each source category and subcategory listed under section 112(c). We issued the NESHAP for BSCP Manufacturing and the NESHAP for Clay Ceramics Manufacturing on May 16, 2003. The two NESHAP were vacated and remanded by the United States Court of Appeals for the District of Columbia Circuit on March 13, 2007. To address the vacatur and remand of the original NESHAP, we are issuing standards for BSCP manufacturing facilities and clay ceramics manufacturing facilities located at major sources.

##### **2. Summary of the Major Provisions**

###### **a. BSCP Manufacturing NESHAP**

The EPA is finalizing MACT emission limits for non-Hg HAP metals (or PM surrogate) and Hg, and a health-based emission limit (HBEL) for acid gases (hydrogen fluoride (HF), hydrogen

chloride (HCl) and chlorine (Cl<sub>2</sub>) for BSCP tunnel kilns. In addition, the EPA is finalizing work practice standards for periodic kilns, dioxins/furans from tunnel kilns, and periods of startup and shutdown for tunnel kilns. To demonstrate compliance with the emission limits, the EPA is requiring initial and repeat 5-year performance testing for the regulated pollutants, parameter monitoring, and daily visible emissions (VE) checks. Owners/operators whose BSCP tunnel kilns are equipped with a fabric filter (FF) (e.g., dry lime injection fabric filter (DIFF), dry lime scrubber/fabric filter (DLS/FF)) have the option of demonstrating compliance using a bag leak detection (BLD) system or daily VE checks.

###### **b. Clay Ceramics Manufacturing NESHAP**

The EPA is finalizing MACT emission limits for Hg, PM (surrogate for non-Hg HAP metals), and dioxins/furans and HBEL for acid gases (HF and HCl) for sanitaryware tunnel kilns and ceramic tile roller kilns. In addition, the EPA is finalizing MACT emission limits for dioxins/furans for ceramic tile spray dryers and floor tile press dryers, MACT emission limits for Hg and PM (surrogate for non-Hg HAP metals) for ceramic tile glaze lines and MACT emission limits for PM (surrogate for non-Hg HAP metals) for sanitaryware glaze spray booths. The EPA is also finalizing work practice standards for shuttle kilns and periods of startup and shutdown. To demonstrate compliance with the emission limits, the EPA is requiring initial and repeat 5-year performance testing for the regulated pollutants, parameter monitoring, and daily VE checks. Owners/operators whose affected sources are equipped with an FF (e.g., DIFF, DLS/FF) have the option of demonstrating compliance using a BLD system or daily VE checks.

##### **3. Costs and Benefits**

Table 1 of this preamble summarizes the costs and benefits of this action for 40 CFR part 63, subpart JJJJ (BSCP Manufacturing NESHAP), while Table 2 of this preamble summarizes the costs of this action for 40 CFR part 63, subpart KKKK (Clay Ceramics Manufacturing NESHAP). See section VI of this preamble for further discussion of the costs and benefits for the BSCP Manufacturing NESHAP and the costs for the Clay Ceramics Manufacturing NESHAP. See section VII.B of this preamble for discussion of the recordkeeping and reporting costs.

TABLE 1—SUMMARY OF THE COSTS AND BENEFITS OF 40 CFR PART 63, SUBPART JJJJJ  
(Millions of 2011 dollars)

Requirement	Capital cost	Annual cost	Net benefit (7 percent discount). <sup>a</sup>
Emission controls .....	\$62.3	\$23.7	\$48 to 150.
Emissions testing .....	2.26	0.552	
Monitoring .....	—	0.352	

<sup>a</sup> Net benefit is the annual cost subtracted from the total monetized benefits (at a 7-percent discount rate). For more information, see section 7 of “Regulatory Impact Analysis: Final Brick and Structural Clay Products NESHAP” in Docket ID No. EPA–HQ–OAR–2013–0291.

TABLE 2—SUMMARY OF THE COSTS OF 40 CFR PART 63, SUBPART KKKKK  
(Millions of 2011 dollars)

Requirement	Capital cost	Annual cost
Emission controls .....	\$0	\$0
Emissions testing .....	0.267	0.0655
Monitoring .....	—	0.0269

*B. Does this action apply to me?*

The regulated categories and entities potentially affected by this action are shown in Table 3 of this preamble:

TABLE 3— NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS ACTION

Category	NAICS Code <sup>a b</sup>	Examples of potentially regulated entities
Industry .....	327120	Brick, structural clay, and extruded tile manufacturing facilities (BSCP Manufacturing NESHAP); and ceramic wall and floor tile manufacturing facilities (Clay Ceramics Manufacturing NESHAP). Vitreous plumbing fixtures (sanitaryware) manufacturing facilities (Clay Ceramics Manufacturing NESHAP).
	327110	
Federal government .....	.....	Not affected.
State/local/tribal government .....	.....	Not affected.

<sup>a</sup> North American Industry Classification System.

<sup>b</sup> Refractories manufacturing is not included in the source categories affected by this action.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether your facility, company, business, organization, etc., is regulated by this action, you should examine the applicability criteria in 40 CFR 63.8385 of subpart JJJJJ (BSCP Manufacturing NESHAP) or 40 CFR 63.8535 of subpart KKKKK (Clay Ceramics Manufacturing NESHAP). If you have any questions regarding the applicability of this action to a particular entity, contact either the delegated authority for the entity or your EPA regional representative as listed in 40 CFR 63.13 of subpart A (General Provisions).

*C. Where can I get a copy of this document and other related information?*

In addition to being available in the docket, an electronic copy of this action is available on the Internet through the EPA’s Technology Transfer Network (TTN) Web site, a forum for information and technology exchange in various

areas of air pollution control. Following signature by the EPA Administrator, the EPA will post a copy of this action at <http://www.epa.gov/ttn/atw/brick/brickpg.html>. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the final rule and key technical documents at this same Web site.

*D. Judicial Review*

Under section 307(b)(1) of the CAA, judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by December 28, 2015. Under section 307(b)(2) of the CAA, the requirements established by these final rules may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that “[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment

(including any public hearing) may be raised during judicial review.” This section also provides a mechanism for us to convene a proceeding for reconsideration, “[i]f the person raising an objection can demonstrate to the EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule.” Any person seeking to make such a demonstration to us should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, EPA WJC North Building, 1200 Pennsylvania Ave. NW., Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

## II. Background Information

### A. What is the statutory authority for the final rule?

Section 112(d) of the CAA requires the EPA to set emissions standards for HAP emitted by sources in each source category and subcategory listed under section 112(c). The MACT standards for existing sources must be at least as stringent as the average emissions limitation achieved by the best performing 12 percent of existing sources (for which the Administrator has emissions information) or the best performing five sources for source categories with less than 30 sources (CAA section 112(d)(3)(A) and (B)). This level of minimum stringency is called the MACT floor. For new sources, MACT standards must be at least as stringent as the control level achieved in practice by the best controlled similar source (CAA section 112(d)(3)). The EPA also must consider more stringent “beyond-the-floor” control options. When considering beyond-the-floor options, the EPA must not only consider the maximum degree of reduction in emissions of HAP, but must also take into account costs, energy and nonair environmental impacts when doing so.

### B. What actions preceded this final rule?

Pursuant to CAA section 112(c)(5), the EPA was originally required to promulgate standards for the BSCP Manufacturing and Clay Ceramics Manufacturing source categories by November 2000. The agency initially promulgated standards for these categories in 2003. See 68 FR 26690 (May 16, 2003). Those standards were challenged and subsequently vacated by the United States Court of Appeals for the District of Columbia Circuit in 2007. See *Sierra Club v. EPA*, 479 F.3d 875, 876 (D.C. Cir. 2007). In 2008, Sierra Club filed suit in the United States Court of Appeals for the District of Columbia Circuit under CAA section 304(a)(2), alleging that the EPA had a continuing mandatory duty to promulgate standards for these categories under CAA section 112 based on the 2000 deadline under CAA section 112(c)(5). The EPA challenged that claim in a motion to dismiss, arguing that the mandatory duty to act by the 2000 deadline was satisfied by the 2003 rule and that the 2007 vacatur of the 2003 rule did not recreate the statutory duty to act by the 2000 deadline. Ultimately, the Court found that the vacatur of the 2003 rule recreated the mandatory duty to set standards by 2000 and held that Sierra Club’s claims could continue. See *Sierra Club v. EPA*, 850 F.Supp.2d 300 (D.D.C.

2012). The EPA and Sierra Club then negotiated a consent decree to settle the litigation and establish proposal and promulgation deadlines for establishing standards for these categories.

Following the 2007 vacatur of the 2003 rule, the EPA began efforts to collect additional data to support new standards for the BSCP and clay ceramics industries. The EPA conducted an initial information collection effort in 2008 to update information on the inventory of affected units, hereafter referred to as “the 2008 EPA survey.” The EPA conducted a second information collection effort in 2010 to obtain additional emissions data and information on each facility’s startup, shutdown, and malfunction (SSM) procedures, hereafter referred to as “the 2010 EPA survey.” The information collected as part of these surveys, and not claimed as CBI by respondents, is available in Docket ID Nos. EPA-HQ-OAR-2013-0290 and EPA-HQ-OAR-2013-0291. In addition, the dockets A-99-30 and OAR-2002-0054 are incorporated by reference for BSCP. The dockets A-2000-48, OAR-2002-0055, and EPA-HQ-OAR-2006-0424 are incorporated by reference for clay ceramics.

On December 18, 2014, the EPA proposed NESHAP for BSCP Manufacturing and NESHAP for Clay Ceramics Manufacturing. See 79 FR 75622 (December 18, 2014). In response to a request from industry, the EPA extended the public comment period for the proposed action from February 17, 2015, to March 19, 2015. See 79 FR 78768 (December 31, 2014). In this action, the EPA is finalizing the rule.

### C. What are the health effects of pollutants emitted from the BSCP Manufacturing and Clay Ceramics Manufacturing source categories?

The final rule protects air quality and promotes the public health by reducing emissions of HAP emitted from BSCP and clay ceramics kilns. Emissions data collected during development of the final rule show that acid gases such as HF, HCl, and Cl<sub>2</sub> represent the predominant HAP emitted by BSCP and clay ceramics kilns, accounting for 99.3 percent of the total HAP emissions. These kilns also emit lesser amounts of other HAP compounds such as HAP metals and dioxins/furans, accounting for about 0.7 percent of total HAP emissions. The HAP metals emitted include antimony, arsenic, beryllium, cadmium, chromium, cobalt, lead, manganese, Hg, nickel and selenium. Exposure to these HAP, depending on exposure duration and levels of exposures, can be associated with a

variety of adverse health effects. These adverse health effects could include chronic health disorders (e.g., irritation of the lung, skin and mucus membranes, effects on the central nervous system and damage to the kidneys) and acute health disorders (e.g., lung irritation and congestion, alimentary effects such as nausea and vomiting, and effects on the kidney and central nervous system). We have classified two of the HAP as human carcinogens (arsenic and chromium VI) and four as probable human carcinogens (cadmium, lead, dioxins/furans and nickel).

## III. Summary of the Final Rule

The following sections summarize the final requirements for the BSCP Manufacturing source category and Clay Ceramics Manufacturing source category. Section IV of this preamble summarizes the major changes since proposal.

### A. What are the final rule requirements for BSCP Manufacturing?

1. What source category is affected by the final rule?

The final NESHAP for BSCP Manufacturing applies to BSCP manufacturing facilities that are located at or are part of a major source of HAP emissions. The BSCP Manufacturing source category includes those facilities that manufacture brick (face brick, structural brick, brick pavers and other brick); clay pipe; roof tile; extruded floor and wall tile; and/or other extruded, dimensional clay products.

2. What are the affected sources?

The affected sources, which are the portions of each source in the category for which we are setting standards, are (1) all tunnel kilns at a BSCP manufacturing facility and (2) each periodic kiln. For purposes of the final BSCP Manufacturing NESHAP, tunnel kilns are defined to include any type of continuous kiln used at BSCP manufacturing facilities, including roller kilns.

Tunnel kilns are fired by natural gas or other fuels, including sawdust. Sawdust firing typically involves the use of a sawdust dryer because sawdust typically is purchased wet and needs to be dried before it can be used as fuel. Consequently, some sawdust-fired tunnel kilns have two process streams, including (1) a process stream that exhausts directly to the atmosphere or to an air pollution control device (APCD), and (2) a process stream in which the kiln exhaust is ducted to a sawdust dryer where it is used to dry sawdust before being emitted to the



atmosphere. Both process streams are subject to the requirements of the final BSCP Manufacturing NESHAP.

The following BSCP process units are not subject to the requirements of the final rule: (1) Kilns that are used exclusively for setting glazes on previously fired products, (2) raw material processing and handling, and (3) dryers. Sources regulated under the Clay Ceramics Manufacturing NESHAP or the Refractories Manufacturing NESHAP are not subject to the requirements of the BSCP Manufacturing NESHAP.

3. Does the final rule apply to me?

This final BSCP Manufacturing NESHAP applies to owners or operators of an affected source at a major source meeting the requirements discussed

previously in this preamble. A major source of HAP emissions is any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, 10 tons per year (tpy) or more of any HAP or 25 tpy or more of any combination of HAP.

4. What emission limitations and work practice standards must I meet?

*Emission limitations.* We are providing a choice of emission limits for total non-Hg HAP metals and Hg for new and existing tunnel kilns in two subcategories based on kiln size. In this final BSCP Manufacturing NESHAP, a large tunnel kiln is defined as a new or existing tunnel kiln with a design capacity of 10 tons per hour (tph) or

greater, and a small tunnel kiln is defined as a new or existing tunnel kiln with a design capacity of less than 10 tph. The options for total non-Hg HAP metals include total non-Hg HAP metals limits in units of pounds per hour (lb/hr) and options for limiting PM as a surrogate for non-Hg HAP metals in units of pounds per ton (lb/ton) or grains per dry standard cubic foot (gr/dscf) at 17-percent oxygen (O<sub>2</sub>). The options for Hg include emission limits in units of lb/ton, lb/hr or micrograms per dry standard cubic meter (µg/dscm) at 17-percent O<sub>2</sub>. We are also issuing an emission limit for HCl-equivalent for all existing and new tunnel kilns at the facility to reduce the acid gases HF, HCl and Cl<sub>2</sub>. The emission limits for acid gases, Hg, and non-Hg HAP metals are presented in Table 4 of this preamble.

TABLE 4—ACID GASES, TOTAL NON-MERCURY HAP METALS AND MERCURY EMISSION LIMITS FOR BRICK AND STRUCTURAL CLAY PRODUCTS TUNNEL KILNS

Subcategory	Acid gases	Total non-Hg HAP metals	Hg
<b>Limits for existing sources</b>			
Large tunnel kilns (≥ 10 tph) .....	—	0.036 lb/ton PM OR 0.0029 gr/dscf PM at 17-percent O <sub>2</sub> OR 0.0057 lb/hr non-Hg HAP metals for each existing tunnel kiln at facility.	4.1 E-05 lb/ton OR 5.5 E-04 lb/hr OR 7.7 µg/dscm at 17- percent O <sub>2</sub> for each existing large tunnel kiln at facility
Small tunnel kilns (< 10 tph) .....	—	0.37 lb/ton PM OR 0.0021 gr/dscf PM at 17-percent O <sub>2</sub> OR 0.11 lb/hr non-Hg HAP metals for each existing tunnel kiln at facility.	3.3 E-04 lb/ton OR 0.0019 lb/hr OR 91 µg/dscm at 17- percent O <sub>2</sub> for each existing small tunnel kiln at facility
All tunnel kilns .....	57 lb/hr HCl-equivalent for collection of all tunnel kilns at facility.	—	—
<b>Limits for new sources</b>			
Large tunnel kilns (≥ 10 tph) .....	—	0.018 lb/ton PM OR 0.0014 gr/dscf PM at 17-percent O <sub>2</sub> OR 0.0057 lb/hr non-Hg HAP metals for each new tunnel kiln at facility.	2.8 E-05 lb/ton OR 3.4 E-04 lb/hr OR 6.2 µg/dscm at 17- percent O <sub>2</sub> for each new large tunnel kiln at facility
Small tunnel kilns (< 10 tph) .....	—	0.030 lb/ton PM OR 0.0021 gr/dscf PM at 17-percent O <sub>2</sub> OR 0.11 lb/hr non-Hg HAP metals for each new tunnel kiln at facility.	3.3 E-04 lb/ton OR 0.0019 lb/hr OR 91 µg/dscm at 17- percent O <sub>2</sub> for each new small tunnel kiln at facility
All tunnel kilns .....	57 lb/hr HCl-equivalent for collection of all tunnel kilns at facility.	—	—

*Work practice standards.* We are issuing work practice standards for BSCP periodic kilns in lieu of HAP emission limits. The work practice standards require developing and using a designed firing time and temperature cycle for each periodic kiln; labeling each periodic kiln with the maximum load (in tons) of product that can be fired in the kiln during a single firing cycle; documenting the total tonnage placed in the kiln for each load to ensure that it is not greater than the

maximum load; developing and implementing maintenance procedures for each kiln that specify the frequency of inspection and maintenance; and developing and maintaining records for each periodic kiln, including logs to document the proper operation and maintenance procedures of the periodic kilns.

We are also issuing work practice standards for BSCP tunnel kilns in lieu of dioxin/furan emission limits. The work practice standards require

maintaining and inspecting the burners and associated combustion controls (as applicable); tuning the specific burner type to optimize combustion; keeping records of each burner tune-up; and submitting a report for each tune-up conducted. As discussed in section III.C.1.a of this preamble, we are also issuing work practice standards for periods of startup and shutdown.

5. What are the testing and initial compliance requirements?

We are requiring that owners or operators of all affected sources subject to emission limits conduct an initial performance test using specified EPA test methods to demonstrate initial compliance with all applicable emission limits. A performance test must be conducted before renewing the facility's 40 CFR part 70 operating permit or at least every 5 years following the initial performance test, as well as when an operating limit parameter value is being revised.

Under the final BSCP Manufacturing NESHAP, the owner or operator is required to measure emissions of HF, HCl, Cl<sub>2</sub>, Hg and PM (or non-Hg HAP metals). We are requiring that the owner or operator measure HF, HCl and Cl<sub>2</sub> using one of the following methods:

- EPA Method 26A, "Determination of Hydrogen Halide and Halogen Emissions from Stationary Sources-Isokinetic Method," 40 CFR part 60, appendix A-8;
- EPA Method 26, "Determination of Hydrogen Chloride Emissions from Stationary Sources," 40 CFR part 60, appendix A-8, when no acid particulate (e.g., HF, HCl or Cl<sub>2</sub> dissolved in water droplets emitted by sources controlled by a wet scrubber) is present;
- EPA Method 320, "Measurement of Vapor Phase Organic and Inorganic Emission by Extractive FTIR" 40 CFR part 63, appendix A, provided the test follows the analyte spiking procedures of section 13 of Method 320, unless the owner or operator can demonstrate that the complete spiking procedure has been conducted at a similar source; or
- Any other alternative method that has been approved by the Administrator under 40 CFR 63.7(f) of the General Provisions.

Following the performance test, the owner or operator must calculate the HCl-equivalent for the kiln using Equation 2 in 40 CFR 63.8445(f)(2)(i). If there are multiple kilns at a facility, the owner or operator must sum the HCl-equivalent for each kiln using Equation 3 in 40 CFR 63.8445(f)(2)(ii) to get the total facility HCl-equivalent and compare this value to the HBEL for acid gases.

As noted above, with respect to non-Hg HAP metals, the owner or operator of a source can choose to meet either a non-Hg HAP metals limit or one of two alternative PM limits. If the owner or operator chooses to comply with one of the two PM emission limits rather than the non-Hg HAP metals limit, we are requiring that the owner or operator measure PM emissions using one of the following methods:

- EPA Method 5, "Determination of Particulate Emissions from Stationary Sources," 40 CFR part 60, appendix A-3;
- EPA Method 29, "Determination of Metals Emissions From Stationary Sources," 40 CFR part 60, appendix A-8; or
- Any other alternative method that has been approved by the Administrator under 40 CFR 63.7(f) of the General Provisions.

If the owner or operator chooses to comply with the non-Hg HAP metals emission limit instead of one of the PM emission limits, the owner or operator must measure non-Hg HAP metals emissions using EPA Method 29 cited above or any other alternative method that has been approved by the Administrator under 40 CFR 63.7(f) of the General Provisions. The owner or operator may also use Method 29 or any other approved alternative method to measure Hg emissions.

The following paragraphs discuss the initial compliance requirements. Prior to the initial performance test, the owner or operator is required to install the continuous parameter monitoring system (CPMS) equipment (as discussed in section III.A.6 of this preamble) to be used to demonstrate continuous compliance with the operating limits. During the initial test, the owner or operator must use the CPMS to establish site-specific operating parameter values that represent the operating limits.

For a DIFF or DLS/FF, we are requiring that the owner or operator ensure that lime in the feed hopper or silo and to the APCD is free-flowing at all times during the HF/HCl/Cl<sub>2</sub> performance test and record the feeder setting (on a per ton of fired product basis) for the three test runs. If the lime feed rate varies, the owner or operator is required to determine the average feed rate from the three test runs. The average of the three test runs establishes the minimum site-specific feed rate operating limit. If there are different average feed rate values during the PM/non-Hg HAP metals and HF/HCl/Cl<sub>2</sub> tests, the highest of the average values becomes the site-specific operating limit. If a BLD system is present, the owner or operator is required to submit analyses and supporting documentation demonstrating conformance with EPA guidance and specifications for BLD systems.

For a stand-alone FF (*i.e.*, no dry sorbent injection or DLS) and a BLD system, we are requiring that the owner or operator submit analyses and supporting documentation demonstrating conformance with EPA

guidance and specifications for BLD systems.

For a dry limestone adsorber (DLA), we are requiring that the owner or operator continuously measure the pressure drop across the DLA during the HF/HCl/Cl<sub>2</sub> performance test and determine the 3-hour block average pressure drop. The average of the three test runs establishes the minimum site-specific pressure drop operating limit. Alternatively, the owner or operator may continuously monitor the bypass stack damper position at least once every 15 minutes during the performance test. The owner or operator also must maintain an adequate amount of limestone in the limestone hopper, storage bin (located at the top of the DLA) and DLA at all times. In addition, the owner or operator is required to establish the limestone feeder setting (on a per ton of fired product basis) 1 week prior to the performance test and maintain the feeder setting for the 1-week period that precedes the performance test and during the performance test. Finally, the owner or operator must document the source and grade of the limestone used during the performance test.

For a wet scrubber, we are requiring that the owner or operator continuously measure the scrubber liquid pH during the HF/HCl/Cl<sub>2</sub> performance test and the scrubber liquid flow rate during both the PM/non-Hg HAP metals and HF/HCl/Cl<sub>2</sub> performance tests. For each wet scrubber parameter, the owner or operator is required to determine and record the average values for the three test runs and the 3-hour block average value. The average of the three test runs establishes the minimum site-specific liquid pH and liquid flow rate operating limits. If different average wet scrubber liquid flow rate values are measured during the PM/non-Hg HAP metals and HF/HCl/Cl<sub>2</sub> tests, the highest of the average values become the site-specific operating limit.

For an activated carbon injection (ACI) system, we are requiring that the owner or operator measure the activated carbon flow rate during the Hg performance test and determine the 3-hour block average flow rate. The average of the three test runs establishes the minimum site-specific activated carbon flow rate operating limit.

For a source with no APCD installed, we are requiring that the owner or operator calculate the maximum potential HCl-equivalent using Equation 4 in 40 CFR 63.8445(g)(1)(i). The owner or operator must use the results from the performance test to determine the emissions at the maximum possible process rate. For example, if the design

capacity of the kiln is 10 tph and the production rate during the performance test was 9 tph, then the test results represent 90 percent of the maximum potential emissions. If there are multiple kilns at a facility, the owner or operator must sum the maximum potential HCl-equivalent for each kiln to get the total facility maximum potential HCl-equivalent and compare this value to the HBEL for acid gases. If the total facility maximum potential HCl-equivalent is greater than the HBEL, we are requiring that the owner or operator determine the maximum process rate for which the total facility maximum potential HCl-equivalent remains at or below the HBEL. If there are multiple kilns, the owner or operator must determine one or more combinations of maximum process rates that result in a total facility maximum potential HCl-equivalent that remains at or below the HBEL. The maximum process rate(s) becomes the operating limit(s) for process rate.

6. What are the continuous compliance requirements?

The final BSCP Manufacturing NESHAP requires that the owner or operator demonstrate continuous compliance with each emission limitation that applies. The owner or operator must follow the requirements in the operation, maintenance and monitoring (OM&M) plan and document conformance with the OM&M plan. The owner or operator must also operate a CPMS to monitor the operating parameters established during the initial performance test as described in the following paragraphs. The CPMS must collect data at least every 15 minutes, including at least three of four equally spaced data values (or at least 75 percent if there are more than four data values per hour) per hour to have a valid hour of data. The owner or operator must operate the CPMS at all times when the process is operating. The owner or operator must also conduct proper maintenance of the CPMS (including inspections, calibrations and validation checks) and maintain an inventory of necessary parts for routine repairs of the CPMS. Using the recorded readings, the owner or operator must calculate and record the 3-hour block average values of each operating parameter. To calculate the average for each 3-hour averaging period, the owner or operator must have at least 75 percent of the recorded readings for that period.

For a DIFF or DLS/FF, we are requiring that the owner or operator demonstrate compliance with the acid gas (HF/HCl/Cl<sub>2</sub>) HBEL by maintaining

free-flowing lime in the feed hopper or silo and to the APCD at all times. If lime is not flowing freely, according to load cell output, carrier gas/lime flow indicator, carrier gas pressure drop measurement system or other system, the owner or operator must promptly initiate and complete corrective actions according to the OM&M plan. The owner or operator must also maintain the feeder setting (on a per ton of fired product basis) at or above the level established during the HF/HCl/Cl<sub>2</sub> performance test and record the feeder setting once each shift.

The final rule provides the option to use either a BLD system or VE monitoring to demonstrate parametric compliance.

For the option of a BLD system, we are requiring that the owner or operator initiate corrective action within 1 hour of a BLD system alarm and complete corrective actions according to the OM&M plan. The owner or operator must also operate and maintain the FF such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period. In calculating this operating time fraction, the owner or operator must not count any alarm time if inspection of the FF demonstrates that no corrective action is required. If corrective action is required, the owner or operator must count each alarm as a minimum of 1 hour. If corrective action is initiated more than 1 hour after an alarm, the owner or operator must count as alarm time the actual amount of time taken to initiate corrective action.

For the option of monitoring VE, we are requiring that if VE are observed during any daily test conducted using Method 22 of 40 CFR part 60, appendix A-7, the owner or operator must promptly conduct an opacity test, according to the procedures of Method 9 of 40 CFR part 60, appendix A-4. If opacity greater than 10 percent is observed, the owner or operator must initiate and complete corrective actions according to the OM&M plan. If no VE are observed in 30 consecutive daily Method 22 tests or no opacity greater than 10 percent is observed during any of the Method 9 tests for any kiln stack, the owner or operator may decrease the frequency of Method 22 testing from daily to weekly for that kiln stack. If VE are observed during any weekly test and opacity greater than 10 percent is observed in the subsequent Method 9 test, the owner or operator must promptly initiate and complete corrective actions according to the OM&M plan, resume testing of that kiln stack following Method 22 of 40 CFR part 60, appendix A-7, on a daily basis,

and maintain that schedule until no VE are observed in 30 consecutive daily tests or no opacity greater than 10 percent is observed during any of the Method 9 tests, at which time the owner or operator may again decrease the frequency of Method 22 testing to a weekly basis.

If greater than 10 percent opacity is observed during any test conducted using Method 9 of 40 CFR part 60, appendix A-4, the owner or operator must report these deviations by following the requirements in 40 CFR 63.8485.

In lieu of conducting VE tests as described above, the owner or operator may conduct a PM test at least once every year following the initial performance test, according to the procedures of Method 5 of 40 CFR part 60, appendix A-3, and the provisions of 40 CFR 63.8445(e) and (f)(1).

For a stand-alone FF, we are requiring that the owner or operator use a BLD system or monitor VE as described above to demonstrate parametric compliance.

For a DLA, we are requiring that the owner or operator demonstrate compliance with the acid gas (HF/HCl/Cl<sub>2</sub>) HBEL by collecting and recording data documenting the DLA pressure drop and reducing the data to 3-hour block averages. The owner or operator must maintain the average pressure drop across the DLA for each 3-hour block period at or above the average pressure drop established during the HF/HCl/Cl<sub>2</sub> performance test. Alternatively, the owner or operator may continuously monitor the bypass stack damper position at least once every 15 minutes during normal kiln operation. Any period in which the bypass damper is opened allowing the kiln exhaust gas to bypass the DLA triggers corrective actions according to the OM&M plan. The owner or operator also must verify that the limestone hopper, storage bin (located at the top of the DLA) and DLA contain an adequate amount of limestone by performing a daily visual check of the limestone hopper and the storage bin. A daily visual check could include one of the following: (1) Conducting a physical check of the hopper; (2) creating a visual access point, such as a window, on the side of the hopper; (3) installing a camera in the hopper that provides continuous feed to a video monitor in the control room; or (4) confirming that load level indicators in the hopper are not indicating the need for additional limestone. If the hopper or storage bin does not contain adequate limestone, the owner or operator must promptly initiate and complete corrective actions

according to the OM&M plan. The owner or operator also must record the limestone feeder setting daily (on a per ton of fired product basis) to verify that the feeder setting is being maintained at or above the level established during the HF/HCl/Cl<sub>2</sub> performance test. The owner or operator also must use the same grade of limestone from the same source as was used during the HF/HCl/Cl<sub>2</sub> performance test and maintain records of the source and type of limestone. Finally, the owner or operator must monitor VE, as described in the previous paragraph.

For a wet scrubber, we are requiring that the owner or operator continuously maintain the 3-hour block averages for scrubber liquid pH and scrubber liquid flow rate at or above the minimum values established during the applicable performance test. Maintaining the 3-hour block average for scrubber liquid pH at or above the minimum value established during the HF/HCl/Cl<sub>2</sub> performance test demonstrates compliance with the acid gas (HF/HCl/Cl<sub>2</sub>) HBEL. Maintaining the 3-hour block average for scrubber liquid flow rate at or above the lowest minimum value established during the PM/non-Hg HAP metals and HF/HCl/Cl<sub>2</sub> performance tests demonstrates compliance with all applicable emission limits by showing that the scrubber is in proper working order.

For an ACI system, we are requiring that the owner or operator demonstrate compliance with the Hg emission limit by continuously monitoring the activated carbon flow rate and maintaining it at or above the operating limit established during the Hg performance test.

For sources with no APCD, we are requiring that the owner or operator monitor VE as described above to demonstrate compliance with the PM/non-Hg HAP metals emission limit. In addition, if the last calculated total facility maximum potential HCl-equivalent was not at or below the HBEL for acid gases, then we are requiring that the owner or operator collect and record data documenting the process rate of the kiln and reduce the data to 3-hour block averages. The owner or operator must maintain the kiln process rate(s) at or below the kiln process rate operating limit(s) that enables the total facility maximum potential HCl-equivalent to remain at or below the HBEL.

#### 7. What are the notification, recordkeeping and reporting requirements?

All new and existing sources are required to comply with certain

requirements of the General Provisions (40 CFR part 63, subpart A), which are identified in Table 10 of subpart JJJJJ. The General Provisions include specific requirements for notifications, recordkeeping and reporting.

Each owner or operator is required to submit a notification of compliance status report, as required by 40 CFR 63.9(h) of the General Provisions. The final BSCP Manufacturing NESHAP requires the owner or operator to include in the notification of compliance status report certifications of compliance with rule requirements. Semiannual compliance reports, as required by 40 CFR 63.10(e)(3) of subpart A, are also required for each semiannual reporting period.

The final BSCP Manufacturing NESHAP requires records to demonstrate compliance with each emission limit and work practice standard. These recordkeeping requirements are specified directly in the General Provisions to 40 CFR part 63 and are identified in Table 8 of subpart JJJJJ.

Specifically, we are requiring that the owner or operator keep the following records:

- All reports and notifications submitted to comply with the final BSCP Manufacturing NESHAP.
- Records of performance tests.
- Records relating to APCD maintenance and documentation of approved routine control device maintenance.
- Continuous monitoring data as required in the final BSCP Manufacturing NESHAP.
- Records of BLD system alarms and corrective actions taken.
- Records of each instance in which the owner or operator did not meet each emission limit (*i.e.*, deviations from operating limits).
- Records of production rates.
- Records of approved alternative monitoring or testing procedures.
- Records of maintenance and inspections performed on the APCD.
- Current copies of the OM&M plan and records documenting conformance.
- Logs of the information required to document compliance with the periodic kiln work practice standard.
- Records of burner tune-ups used to comply with the dioxin/furan work practice standard for tunnel kilns.
- Logs of the information required to document compliance with the startup and shutdown work practice standards.
- Records of each malfunction and the corrective action taken.
- Records of parameters and procedures followed for work practice standards.

We are also requiring that the owner or operator submit the following reports and notifications:

- Notifications required by the General Provisions.
- Initial Notification no later than 120 calendar days after the affected source becomes subject to this subpart.
- Notification of Intent to conduct performance tests and/or other compliance demonstration at least 60 calendar days before the performance test and/or other compliance demonstration is scheduled.
- Notification of Compliance Status 60 calendar days following completion of a compliance demonstration that includes a performance test.
- Notification of Compliance Status 30 calendar days following completion of a compliance demonstration that does not include a performance test (*i.e.*, compliance demonstrations for the work practice standards).
- Compliance reports semi-annually, including a report of the most recent burner tune-up conducted to comply with the dioxin/furan work practice standard and a report of each malfunction resulting in an exceedance and the corrective action taken.
- Results of each performance test within 60 calendar days of completing the test, submitted to the EPA by direct computer-to-computer electronic transfer via EPA-provided software for data collected using supported test methods (see section III.E of this preamble for more information).

#### B. What are the final rule requirements for Clay Ceramics Manufacturing?

##### 1. What source category is affected by the final rule?

This final rule for Clay Ceramics Manufacturing applies to clay ceramics manufacturing facilities that are located at or are part of a major source of HAP emissions. The Clay Ceramics Manufacturing source category includes those facilities that manufacture pressed floor tile, pressed wall tile and other pressed tile; or sanitaryware (*e.g.*, toilets and sinks).

##### 2. What are the affected sources?

The affected sources, which are the portions of each source in the category for which we are setting standards, are (1) each ceramic tile roller kiln; (2) each floor tile press dryer; (3) each ceramic tile spray dryer; (4) each ceramic tile glaze line using glaze spraying; (5) each sanitaryware tunnel kiln; (6) each sanitaryware shuttle kiln; and (7) each sanitaryware glaze spray booth.

The following clay ceramics process units are not subject to the requirements

of the final rule: (1) Tunnel, roller or shuttle kilns that are used exclusively for refriring; (2) tunnel, roller or shuttle kilns that are used exclusively for setting glazes on previously fired products; (3) glaze spray operations that are used exclusively with those kilns listed in items 1 and 2 above; (4) process units listed in items 1 through 3 above that are permitted to, but do not, process first-fire ware, until such time as they begin to process first-fire ware; (5) refire shuttle kilns that fire no more than four batches per year of first-fire ware; (6) glaze spray operations that on average use wet glazes containing less than 0.1 (weight) percent metal HAP (dry weight basis) per spray booth over an entire calendar year; (7) raw material processing and handling; (8) wall tile press dryers; and (9) sanitaryware ware dryers. Sources regulated under the BSCP Manufacturing NESHAP or the

Refractories Manufacturing NESHAP are not subject to the requirements of the Clay Ceramics Manufacturing NESHAP.

3. Does the final rule apply to me?

This final Clay Ceramics Manufacturing NESHAP applies to owners or operators of an affected source at a major source meeting the requirements discussed previously in this preamble. A major source of HAP emissions is any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, 10 tpy or more of any HAP or 25 tpy or more of any combination of HAP.

4. What emission limitations and work practice standards must I meet?

*Emission limitations.* We are issuing emission limits for PM as a surrogate for

total non-Hg HAP metals (in units of lb/ton) for all new and existing ceramic tile roller kilns, sanitaryware tunnel kilns and ceramic tile and sanitaryware glazing operations. We are issuing emission limits for Hg (lb/ton) for all new and existing ceramic tile roller kilns, ceramic tile glaze lines and sanitaryware tunnel kilns. We are issuing emission limits for dioxin/furan (nanograms of 2,3,7,8-tetrachlorodibenzo-p-dioxin toxic equivalents (TEQ) per kilogram (ng/kg)) for all new and existing ceramic tile roller kilns, sanitaryware tunnel kilns, floor tile press dryers and ceramic tile spray dryers. We are also issuing an emission limit for HCl-equivalent for all existing and new roller and tunnel kilns at each facility to reduce the acid gases HF and HCl. The emission limits are presented in Table 5 of this preamble.

TABLE 5—EMISSION LIMITS FOR CLAY CERAMICS SOURCES

Subcategory	Acid gases (lb/hr HCl-equivalent) <sup>a</sup>	Hg (lb/ton)	PM <sup>b</sup> (lb/ton)	Dioxins/furans (ng/kg) <sup>c</sup>
<b>Limits for existing sources</b>				
Floor tile roller kilns .....	140	1.3 E-04	0.13	2.8
Floor tile press dryers .....				0.024
Floor tile spray dryers .....				19
Wall tile roller kilns .....	140	2.1 E-04	0.37	0.22
Wall tile spray dryers .....				0.058
Tile glaze lines .....		1.6 E-04	1.9	
First-fire sanitaryware tunnel kilns .....	140	2.6 E-04	0.34	3.3
Sanitaryware manual glaze application .....			35	
Sanitaryware spray machine glaze application .....			13	
Sanitaryware robot glaze application .....			8.9	
<b>Limits for new sources</b>				
Floor tile roller kilns .....	140	3.9 E-05	0.037	1.3
Floor tile press dryers .....				0.024
Floor tile spray dryers .....				0.071
Wall tile roller kilns .....	140	2.1 E-04	0.37	0.22
Wall tile spray dryers .....				0.058
Tile glaze lines .....		1.6 E-04	0.61	
First-fire sanitaryware tunnel kilns .....	140	1.3 E-04	0.095	0.99
Sanitaryware manual glaze application .....			3.9	
Sanitaryware spray machine glaze application .....			3.2	
Sanitaryware robot glaze application .....			2.3	

<sup>a</sup> Limit applies to collection of all kilns at facility.  
<sup>b</sup> PM is a surrogate for non-Hg HAP metals.  
<sup>c</sup> ng/kg = nanograms per kilogram.

*Work practice standards.* We are issuing work practice standards in lieu of emission limits for acid gases (HF and HCl), Hg and non-Hg HAP metals for sanitaryware shuttle kilns. The work practice standards require using natural gas (or equivalent) as kiln fuel except during periods of natural gas curtailment or supply interruption; developing and using a designed firing time and temperature cycle for each shuttle kiln; labeling each shuttle kiln

with the maximum load (in tons) of throughput (greenware) that can be fired in the kiln during a single firing cycle; documenting the total tonnage of greenware placed in the kiln for each load to ensure that it is not greater than the maximum load; developing and implementing maintenance procedures for each kiln that specify the frequency of inspection and maintenance; and developing and maintaining records for each shuttle kiln, including logs to

document the proper operation and maintenance procedures of the shuttle kilns. As discussed in section III.C.1.b of this preamble, we are also issuing work practice standards for periods of startup and shutdown.

5. What are the testing and initial compliance requirements?

We are requiring that owners or operators of all affected sources subject to emission limits conduct an initial

performance test using specified EPA test methods to demonstrate initial compliance with all applicable emission limits. A performance test must be conducted before renewing the facility's 40 CFR part 70 operating permit or at least every 5 years following the initial performance test, as well as when an operating limit parameter value is being revised.

Under the final Clay Ceramics Manufacturing NESHAP, the owner or operator is required to measure emissions of HF, HCl, Hg, PM (as a surrogate for non-Hg HAP metals) and dioxins/furans. The owner or operator must measure HF and HCl from ceramic tile roller kilns and sanitaryware first-fire tunnel kilns using one of the following methods:

- EPA Method 26A, "Determination of Hydrogen Halide and Halogen Emissions from Stationary Sources-Isokinetic Method," 40 CFR part 60, appendix A-8;

- EPA Method 26, "Determination of Hydrogen Chloride Emissions from Stationary Sources," 40 CFR part 60, appendix A-8, when no acid particulate (e.g., HF or HCl dissolved in water droplets emitted by sources controlled by a wet scrubber) is present;

- EPA Method 320, "Measurement of Vapor Phase Organic and Inorganic Emission by Extractive FTIR" 40 CFR part 63, appendix A, provided the test follows the analyte spiking procedures of section 13 of Method 320, unless the owner or operator can demonstrate that the complete spiking procedure has been conducted at a similar source; or

- Any other alternative method that has been approved by the Administrator under 40 CFR 63.7(f) of the General Provisions.

Following the performance test, the owner or operator must calculate the HCl-equivalent for the kiln using Equation 4 in 40 CFR 63.8595(f)(4)(i). If there are multiple kilns at a facility, the owner or operator must sum the HCl-equivalent for each kiln using Equation 5 in 40 CFR 63.8595(f)(4)(ii) to get the total facility HCl-equivalent and compare this value to the HBEL.

We are requiring that the owner or operator measure PM emissions from ceramic tile roller kilns and sanitaryware first-fire tunnel kilns using one of the following methods:

- EPA Method 5, "Determination of Particulate Emissions from Stationary Sources," 40 CFR part 60, appendix A-3;

- EPA Method 29, "Determination of Metals Emissions From Stationary Sources," 40 CFR part 60, appendix A-8; or

- Any other alternative method that has been approved by the Administrator under 40 CFR 63.7(f) of the General Provisions.

Method 29 or any other approved alternative method may also be used to measure Hg emissions from ceramic tile roller kilns, ceramic tile glaze lines and sanitaryware first-fire tunnel kilns.

We are requiring that the owner or operator measure PM emissions from ceramic tile and sanitaryware glaze spray booths using EPA Method 5 or any other alternative method that has been approved by the Administrator under 40 CFR 63.7(f) of the General Provisions.

We are also requiring that the owner or operator measure dioxin/furan emissions from ceramic tile roller kilns and spray dryers, floor tile press dryers and sanitaryware first-fire tunnel kilns using EPA Method 23, "Determination of Polychlorinated Dibenzo-p-Dioxins and Polychlorinated Dibenzofurans From Stationary Sources," 40 CFR part 60, appendix A-7 or any other alternative method that has been approved by the Administrator under 40 CFR 63.7(f) of the General Provisions.

The following paragraphs discuss the initial compliance requirements. Prior to the initial performance test, the owner or operator is required to install the CPMS equipment (as discussed in section III.B.6 of this preamble) to be used to demonstrate continuous compliance with the operating limits. During the initial test, the owner or operator must use the CPMS to establish site-specific operating parameter values that represent the operating limits.

For a DIFF or DLS/FF, we are requiring that the owner or operator ensure that lime in the feed hopper or silo and to the APCD is free-flowing at all times during the HF/HCl performance test and record the feeder setting (on a per ton of fired product basis) for the three test runs. If the lime feed rate varies, the owner or operator is required to determine the average feed rate from the three test runs. The average of the three test runs establishes the minimum site-specific feed rate operating limit. If there are different average feed rate values during the PM and HF/HCl tests, the highest of the average values becomes the site-specific operating limit. If a BLD system is present, the owner or operator is required to submit analyses and supporting documentation demonstrating conformance with EPA guidance and specifications for BLD systems.

For a stand-alone FF (*i.e.*, no dry sorbent injection or DLS) and a BLD system, we are requiring that the owner

or operator submit analyses and supporting documentation demonstrating conformance with EPA guidance and specifications for BLD systems.

For a wet scrubber, we are requiring that the owner or operator continuously measure the scrubber liquid pH during the HF/HCl performance test and the scrubber liquid flow rate during both the PM and HF/HCl performance tests. For each wet scrubber parameter, the owner or operator is required to determine and record the average values for the three test runs and the 3-hour block average value. The average of the three test runs establishes the minimum site-specific liquid pH and liquid flow rate operating limits. If different average wet scrubber liquid flow rate values are measured during the PM and HF/HCl tests, the highest of the average values become the site-specific operating limits.

For an ACI system, we are requiring that the owner or operator measure the activated carbon flow rate during the Hg and dioxin/furan performance tests and determine the 3-hour block average flow rate. The average of the three test runs establishes the minimum site-specific activated carbon flow rate operating limit. If different average activated carbon flow rate values are measured during the Hg and dioxin/furan tests, the highest of the average values becomes the site-specific operating limit.

If the owner or operator intends to comply with the dioxin/furan emission limit without an ACI system, we are requiring that the owner or operator measure the stack temperature of the tunnel or roller kiln during the dioxin/furan performance test. The highest 4-hour average stack temperature of the three test runs establishes the maximum site-specific operating limit. The owner or operator must also measure the operating temperatures of the ceramic tile spray dryer and floor tile press dryer during the dioxin/furan performance test and determine the 3-hour block average temperature. The average of the three test runs establishes the site-specific operating limit.

For sources with no APCD installed, we are requiring that the owner or operator calculate the maximum potential HCl-equivalent using Equation 6 in 40 CFR 63.8595(g)(1)(i). The owner or operator must use the results from the performance test to determine the emissions at the maximum possible process rate. For example, if the design capacity of the tunnel or roller kiln is 10 tph and the production rate during the performance test was 9 tph, then the test results represent 90 percent of the

maximum potential emissions. If there are multiple kilns at a facility, the owner or operator must sum the maximum potential HCl-equivalent for each kiln to get the total facility maximum potential HCl-equivalent and compare this value to the HBEL for acid gases. If the total facility maximum potential HCl-equivalent is greater than the HBEL, we are requiring that the owner or operator determine the maximum process rate for which the total facility maximum potential HCl-equivalent remains at or below the HBEL. If there are multiple kilns, the owner or operator must determine one or more combinations of maximum process rates that result in a total facility maximum potential HCl-equivalent that remains at or below the HBEL. The maximum process rate(s) becomes the operating limit(s) for process rate. We are also requiring that the owner or operator measure the stack temperature of the tunnel or roller kiln during the dioxin/furan performance test. The highest 4-hour average stack temperature of the three test runs establishes the maximum site-specific operating limit. The owner or operator must also measure the operating temperatures of the ceramic tile spray dryer and floor tile press dryer during the dioxin/furan performance test and determine the 3-hour block average temperature. The average of the three test runs establishes the site-specific operating limit.

6. What are the continuous compliance requirements?

The final Clay Ceramics Manufacturing NESHAP requires that the owner or operator demonstrate continuous compliance with each emission limitation that applies. The owner or operator must follow the requirements in the OM&M plan and document conformance with the OM&M plan. The owner or operator must also operate a CPMS to monitor the operating parameters established during the initial performance test as described in the following paragraphs. The CPMS must collect data at least every 15 minutes, including at least three of four equally spaced data values (or at least 75 percent if there are more than four data values per hour) per hour to have a valid hour of data. The owner or operator must operate the CPMS at all times when the process is operating. The owner or operator must also conduct proper maintenance of the CPMS, including inspections, calibrations and validation checks, and maintain an inventory of necessary parts for routine repairs of the CPMS. Using the recorded readings, the owner or

operator must calculate and record the 3-hour block average values of each operating parameter. To calculate the average for each 3-hour averaging period, the owner or operator must have at least 75 percent of the recorded readings for that period.

For a DIFF or DLS/FF, we are requiring that the owner or operator demonstrate compliance with the acid gas (HF/HCl) HBEL by maintaining free-flowing lime in the feed hopper or silo and to the APCD at all times. If lime is found not to be free flowing via the output of a load cell, carrier gas/lime flow indicator, carrier gas pressure drop measurement system or other system, the owner or operator must promptly initiate and complete corrective actions according to the OM&M plan. The owner or operator must also maintain the feeder setting (on a per ton of throughput basis) at or above the level established during the performance test and record the feeder setting once each shift.

For a DIFF or DLS/FF, the final rule provides the option to use either a BLD system or VE monitoring to demonstrate parametric compliance.

For the option of a BLD system, we are requiring that the owner or operator initiate corrective action within 1 hour of a BLD system alarm and complete corrective actions according to the OM&M plan. The owner or operator must also operate and maintain the FF such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period. In calculating this operating time fraction, if inspection of the FF demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm must be counted as a minimum of 1 hour and if corrective action is initiated more than 1 hour after an alarm, the alarm time must be counted as the actual amount of time taken to initiate corrective action.

For the option of monitoring VE, we are requiring that the owner or operator perform daily, 15-minute VE observations in accordance with the procedures of EPA Method 22, "Visual Determination of Fugitive Emissions from Material Sources and Smoke Emissions from Flares," 40 CFR part 60, appendix A-7. During the VE observations, the source must be operating under normal conditions. If VE are observed, the owner or operator must promptly initiate and complete corrective actions according to the OM&M plan. If no VE are observed in 30 consecutive daily EPA Method 22 tests, the owner or operator may decrease the frequency of EPA Method

22 testing from daily to weekly for that source. If VE are observed during any weekly test, the owner or operator must promptly initiate and complete corrective actions according to the OM&M plan and the owner or operator must resume EPA Method 22 testing of that source on a daily basis until no VE are observed in 30 consecutive daily tests, at which time the owner or operator may again decrease the frequency of EPA Method 22 testing to a weekly basis.

For a stand-alone FF, we are requiring that the owner or operator use a BLD system or monitor VE as described above to demonstrate parametric compliance.

For a wet scrubber on a tunnel or roller kiln, we are requiring that the owner or operator continuously maintain the 3-hour block averages for scrubber liquid pH and scrubber liquid flow rate at or above the minimum values established during the applicable performance test. Maintaining the 3-hour block average for scrubber liquid pH at or above the minimum values established during the HF/HCl performance test demonstrates compliance with the acid gas (HF/HCl) HBEL. Maintaining the 3-hour block average for scrubber liquid flow rate at or above the lowest minimum value established during the PM and HF/HCl performance tests demonstrates compliance with all applicable emission limits by showing that the scrubber is in proper working order.

For an ACI system, we are requiring that the owner or operator demonstrate compliance with the Hg and dioxin/furan emission limits by continuously monitoring the activated carbon flow rate and maintaining it at or above the lowest minimum value established during the Hg and dioxin/furan performance tests.

If the owner or operator intends to comply with the dioxin/furan emission limit without an ACI system, we are requiring that the owner or operator demonstrate compliance by continuously monitoring the stack temperature of the tunnel or roller kiln and the operating temperature of the ceramic tile spray dryer and floor tile press dryer and maintaining it at or below the highest 4-hour average temperature during the dioxin/furan performance test for the tunnel or roller kiln, at or above the average temperature during the dioxin/furan performance test for the ceramic tile spray dryer, and at or below the average temperature during the dioxin/furan performance test for the floor tile press dryer.

For a wet scrubber on a spray glazing operation, we are requiring that the



owner or operator continuously maintain the 3-hour block averages for scrubber pressure drop and scrubber liquid flow rate at or above the minimum values established during the applicable performance test.

Maintaining the 3-hour block average for scrubber pressure drop at or above the minimum value established during the PM performance test demonstrates compliance with the PM emission limit. Maintaining the 3-hour block average for scrubber liquid flow rate at or above the minimum value established during the PM performance test demonstrates compliance with the PM emission limit by showing that the scrubber is in proper working order.

For a water curtain on a spray glazing operation, we are requiring that the owner or operator demonstrate compliance with the PM emission limit by conducting a daily inspection to verify the presence of water flow to the wet control system, conducting weekly visual inspections of the system ductwork and control equipment for leaks and conducting annual inspections of the interior of the control equipment (if applicable) to determine the structural integrity and condition of the control equipment.

For baffles on a spray glazing operation, we are requiring that the owner or operator demonstrate compliance with the PM emission limit by conducting an annual visual inspection of the baffles to confirm the baffles are in place.

For a source with no APCD, we are requiring that, to demonstrate compliance with the PM emission limit, the owner or operator monitor VE as described above. We are also requiring that, to demonstrate compliance with the dioxin/furan emission limit, the owner or operator continuously monitor the stack temperature of the tunnel or roller kiln and operating temperature of the ceramic tile spray dryer and floor tile press dryer and maintain it at or below the highest 4-hour average stack temperature during the dioxin/furan performance test for the tunnel or roller kiln, at or above the average operating temperature during the dioxin/furan performance test for the ceramic tile spray dryer, and at or below the average operating temperature during the dioxin/furan performance test for the floor tile press dryer. In addition, if the last calculated total facility maximum potential HCl-equivalent was not at or below the HBEL for acid gases, then we are requiring that the owner or operator collect and record data documenting the process rate of the tunnel or roller kiln and reduce the data to 3-hour block averages. The owner or operator must

maintain the kiln process rate(s) at or below the kiln process rate operating limit(s) that enables the total facility maximum potential HCl-equivalent to remain at or below the HBEL.

7. What are the notification, recordkeeping and reporting requirements?

All new and existing sources are required to comply with certain requirements of the General Provisions (40 CFR part 63, subpart A), which are identified in Table 11 of subpart KKKKK. The General Provisions include specific requirements for notifications, recordkeeping and reporting.

Each owner or operator is required to submit a notification of compliance status report, as required by 40 CFR 63.9(h) of the General Provisions. This final Clay Ceramics Manufacturing NESHAP requires the owner or operator to include in the notification of compliance status report certifications of compliance with rule requirements. Semiannual compliance reports, as required by 40 CFR 63.10(e)(3) of subpart A, are also required for each semiannual reporting period.

This final Clay Ceramics Manufacturing NESHAP requires records to demonstrate compliance with each emission limit and work practice standard. These recordkeeping requirements are specified directly in the General Provisions to 40 CFR part 63 and are identified in Table 9 of subpart KKKKK.

Specifically, we are requiring that the owner or operator must keep the following records:

- All reports and notifications submitted to comply with this final Clay Ceramics Manufacturing NESHAP.
- Records of performance tests.
- Records relating to APCD maintenance and documentation of approved routine control device maintenance.
- Continuous monitoring data as required in this final Clay Ceramics Manufacturing NESHAP.
- Records of BLD system alarms and corrective actions taken.
- Each instance in which the owner or operator did not meet each emission limit (*i.e.*, deviations from operating limits).
- Records of production rates.
- Records of approved alternative monitoring or testing procedures.
- Records of maintenance and inspections performed on the APCD.
- Current copies of the OM&M plan and records documenting conformance.
- Logs of the information required to document compliance with the shuttle kiln work practice standard.

- Logs of the information required to document compliance with the startup and shutdown work practice standards.

- Records of each malfunction and the corrective action taken.

- Records of parameters and procedures followed for work practice standards.

We are also requiring that the owner or operator submit the following reports and notifications:

- Notifications required by the General Provisions.

- Initial Notification no later than 120 calendar days after the affected source becomes subject to this subpart.

- Notification of Intent to conduct performance tests and/or other compliance demonstration at least 60 calendar days before the performance test and/or other compliance demonstration is scheduled.

- Notification of Compliance Status 60 calendar days following completion of a compliance demonstration that includes a performance test.

- Notification of Compliance Status 30 calendar days following completion of a compliance demonstration that does not include a performance test (*i.e.*, compliance demonstration for the work practice standard).

- Compliance reports semi-annually, including a report of each malfunction resulting in an exceedance and the corrective action taken.

- Report of alternative fuel use within 10 working days after terminating use of the alternative fuel.

- Results of each performance test within 60 calendar days of completing the test, submitted to the EPA by direct computer-to-computer electronic transfer via EPA-provided software for data collected using supported test methods (see section III.E of this preamble for more information).

*C. What are the requirements during periods of startup, shutdown, and malfunction?*

In its 2008 decision in *Sierra Club v. EPA*, 551 F.3d 1019 (D.C. Cir. 2008), the United States Court of Appeals for the District of Columbia Circuit vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the Court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some section 112 standards apply continuously.

### 1. Periods of Startup or Shutdown

Consistent with *Sierra Club v. EPA*, the EPA has established standards in this rule that apply at all times. In establishing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained in the preamble to the proposed rule and in sections IV.A.4 and IV.B.2 of this preamble, has established alternate standards for those periods.

#### a. BSCP Manufacturing

The EPA is issuing the work practice standards described in this paragraph for periods of startup and shutdown for BSCP tunnel kilns with APCD. As a first step, the owner or operator is required to determine the APCD minimum inlet temperature and the startup kiln car push rate of the product. For startup, the owner or operator is required to vent the exhaust from the kiln through the APCD at all times when the exhaust temperature is at or above the minimum inlet temperature. In addition, the owner or operator may not exceed the startup kiln car push rate until the kiln exhaust is vented to the APCD. For shutdown, the owner or operator is required to vent the exhaust from the kiln through the APCD until the kiln exhaust temperature falls below the APCD minimum inlet temperature. In addition, the kiln car push rate is to be steadily decreased to zero as the kiln cools. No additional loaded kiln cars may be introduced into the kiln once the kiln exhaust temperature falls below the APCD minimum inlet temperature. When the kiln exhaust is being vented through the APCD, the owner or operator is required to comply with the applicable continuous compliance requirements described in section III.A.6 of this preamble.

The EPA is issuing similar work practice standards for periods of startup and shutdown for BSCP tunnel kilns without an APCD as well. As a first step, the owner or operator is required to determine the product-specific kiln temperature profile and the startup kiln car push rate of the product. For startup, the startup kiln car push rate may not be exceeded until the kiln reaches the product-specific kiln temperature profile. For shutdown, the kiln car push rate is to be steadily decreased to zero as the kiln cools. No additional loaded kiln cars may be introduced into the kiln once the kiln falls below the product-specific kiln temperature profile. When the kiln production rate is greater than the startup kiln car push rate, the owner or operator is required to comply with the applicable

continuous compliance requirements described in section III.A.6 of this preamble.

#### b. Clay Ceramics Manufacturing

The EPA is issuing the work practice standards described in this paragraph for periods of startup and shutdown for ceramic tile roller kilns, floor tile press dryers, ceramic tile spray dryers and sanitaryware tunnel kilns with APCD. As a first step, the owner or operator is required to determine the APCD minimum inlet temperature and the startup production rate of the product. For startup, the owner or operator is required to vent the exhaust from the kiln or dryer through the APCD at all times when the exhaust temperature is at or above the minimum inlet temperature. In addition, the owner or operator may not exceed the startup production rate of the product until the kiln or dryer exhaust is being vented through the APCD. For shutdown, the owner or operator is required to vent the exhaust from the kiln or dryer through the APCD until the exhaust temperature falls below the APCD minimum inlet temperature. In addition, the production rate is to be steadily decreased to zero as the kiln or dryer cools. No additional throughput may be introduced to the kiln, press dryer and spray dryer once the exhaust temperature falls below the APCD minimum inlet temperature. When the exhaust is being vented through the APCD, the owner or operator is required to comply with the applicable continuous compliance requirements described in section III.B.6 of this preamble.

The EPA is also issuing work practice standards for periods of startup and shutdown for ceramic tile roller kilns, floor tile press dryers, ceramic tile spray dryers and sanitaryware tunnel kilns without an APCD. As a first step, the owner or operator is required to determine the product-specific kiln or dryer temperature profile and the startup production rate of the product. For startup, the startup production rate may not be exceeded until the kiln or dryer exhaust temperature reaches the product-specific temperature profile. For shutdown, the production rate is to be steadily decreased to zero as the kiln or dryer cools. No additional throughput may be introduced to the kiln, press dryer and spray dryer once the kiln, press dryer or spray dryer falls below the product-specific temperature profile. When the kiln or dryer production rate is greater than the startup production rate, the owner or operator is required to comply with the applicable continuous compliance requirements

described in section III.B.6 of this preamble.

### 2. Periods of Malfunction

Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead they are by definition sudden, infrequent and not reasonably preventable failures of emissions control, process or monitoring equipment (40 CFR 63.2) (Definition of malfunction). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards. Under section 112, emissions standards for new sources must be no less stringent than the level "achieved" by the best controlled similar source and for existing sources generally must be no less stringent than the average emission limitation "achieved" by the best performing 12 percent of sources in the category. There is nothing in CAA section 112 that directs the agency to consider malfunctions in determining the level "achieved" by the best performing sources when setting emission standards. As the DC Circuit has recognized, the phrase "average emissions limitation achieved by the best performing 12 percent of" sources "says nothing about how the performance of the best units is to be calculated." *Nat'l Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1141 (D.C. Cir. 2013). While the EPA accounts for variability in setting emissions standards, nothing in CAA section 112 requires the agency to consider malfunctions as part of that analysis. A malfunction should not be treated in the same manner as the type of variation in performance that occurs during routine operations of a source. A malfunction is a failure of the source to perform in a "normal or usual manner" and no statutory language compels the EPA to consider such events in setting section CAA 112 standards.

Further, accounting for malfunctions in setting emission standards would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree, and duration of various malfunctions that might occur. As such, the performance of units that are malfunctioning is not "reasonably" foreseeable. See, e.g., *Sierra Club v. EPA*, 167 F.3d 658, 662 (D.C. Cir. 1999) ("The EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a

problem. We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to 'invest the resources to conduct the perfect study.'") *See also, Weyerhaeuser v. Costle*, 590 F.2d 1011, 1058 (D.C. Cir. 1978) ("In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation."). In addition, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an APCD with 99-percent removal goes off-line as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state type unit that would take days to shut down, the source would go from 99-percent control to zero control until the APCD was repaired. The source's emissions during the malfunction would be 100 times higher than during normal operations. As a result, the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret CAA section 112 to avoid such a result. The EPA's approach to malfunctions is consistent with CAA section 112 and is a reasonable interpretation of the statute.

In the event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source's failure to comply with the CAA section 112(d) standard was, in fact, sudden, infrequent, not reasonably preventable and was not instead caused in part by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction).

If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

In summary, the EPA interpretation of the CAA and, in particular, section 112 is reasonable and encourages practices that will avoid malfunctions. Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations.

#### *D. What are the effective and compliance dates of the standards?*

The NESHAP for BSCP Manufacturing and Clay Ceramics Manufacturing are effective on December 28, 2015.

If the initial startup of the affected source is after December 18, 2014, but before December 28, 2015, then the compliance date is no later than December 28, 2015. If the initial startup of the affected source is after December 28, 2015, then the compliance date is immediately upon initial startup of the affected source. The compliance date for existing affected sources is no later than December 26, 2018.

The initial performance test must be conducted within 180 calendar days after the compliance date specified in 40 CFR 63.8395 for affected sources of BSCP manufacturing and 40 CFR 63.8545 for affected sources of clay ceramics manufacturing, according to the provisions in 40 CFR 60.7(a)(2). The first of the 5-year repeat tests must be conducted no later than 5 years following the initial performance test, and thereafter within 5 years from the date of the previous performance test. The date to submit performance test data through the Electronic Reporting Tool (ERT) is within 60 calendar days after the date of completing each performance test.

#### *E. What are the requirements for submission of performance test data to the EPA?*

The EPA is requiring owners or operators of BSCP and clay ceramics facilities to submit electronic copies of certain required performance test reports through the EPA's Central Data Exchange (CDX) using the Compliance

and Emissions Data Reporting Interface (CEDRI). As stated in the proposed preamble, the EPA believes that the electronic submittal of the reports addressed in this rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability, will further assist in the protection of public health and the environment and will ultimately result in less burden on the regulated community. Electronic reporting can also eliminate paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors and providing data quickly and accurately to the affected facilities, air agencies, the EPA and the public.

As mentioned in the preamble of the proposal, the EPA Web site that stores the submitted electronic data, WebFIRE, will be easily accessible to everyone and will provide a user-friendly interface that any stakeholder could access. By making the records, data and reports addressed in this rulemaking readily available, the EPA, the regulated community and the public will benefit when the EPA conducts its CAA-required technology and risk-based reviews. As a result of having reports readily accessible, our ability to carry out comprehensive reviews will be increased and achieved within a shorter period of time.

We anticipate fewer or less substantial information collection requests (ICRs) in conjunction with prospective CAA-required technology and risk-based reviews may be needed. We expect this to result in a decrease in time spent by industry to respond to data collection requests. We also expect the ICRs to contain less extensive stack testing provisions, as we will already have stack test data electronically. Reduced testing requirements would be a cost savings to industry. The EPA should also be able to conduct these required reviews more quickly. While the regulated community may benefit from a reduced burden of ICRs, the general public benefits from the agency's ability to provide these required reviews more quickly, resulting in increased public health and environmental protection.

Air agencies could benefit from more streamlined and automated review of the electronically submitted data. Having reports and associated data in electronic format will facilitate review through the use of software "search" options, as well as the downloading and analyzing of data in spreadsheet format. The ability to access and review air emission report information electronically will assist air agencies to

more quickly and accurately determine compliance with the applicable regulations, potentially allowing a faster response to violations which could minimize harmful air emissions. This benefits both air agencies and the general public.

For a more thorough discussion of electronic reporting required by this rule, see the discussion in the preamble of the proposal. In summary, in addition to supporting regulation development, control strategy development and other air pollution control activities, having an electronic database populated with performance test data will save industry, air agencies, and the EPA significant time, money, and effort while improving the quality of emission inventories, air quality regulations, and enhancing the public's access to this important information.

*F. What materials are being incorporated by reference under 1 CFR part 51?*

In this final rule, the EPA is including regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is incorporating by reference the following documents described in the amendments to 40 CFR 63.14:

- ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], (Issued August 31, 1981), IBR approved for Table 4 to subpart JJJJJ and Table 4 to subpart KKKKK. To correct an earlier, inadvertent error that exists in the CFR, we are also adding back in the IBR approval for Table 4 to subpart JJJJJ.

- ASTM D6348–03 (Reapproved 2010), Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, including Annexes A1 through A8, (Approved October 1, 2010), IBR approved for Tables 4 and 5 to subpart JJJJJ and Tables 4 and 6 to subpart KKKKK.

- ASTM D6784–02 (Reapproved 2008), Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method), (Approved April 1, 2008), IBR approved for Tables 4 and 5 to subpart JJJJJ and Tables 4 and 6 to subpart KKKKK.

- ASTM D6735–01 (Reapproved 2009), Standard Test Method for Measurement of Gaseous Chlorides and Fluorides from Mineral Calcining Exhaust Sources—Impinger Method, IBR approved for Tables 4 and 5 to

subpart JJJJJ and Tables 4 and 6 to subpart KKKKK.

- EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997, IBR approved for 40 CFR 63.8450(e)(1), (9), and (10) and 40 CFR 63.8600(e)(1), (9), and (10).

The EPA has made, and will continue to make, these documents generally available electronically through [www.regulations.gov](http://www.regulations.gov) and/or in hard copy at the appropriate EPA office (see the ADDRESSES section of this preamble for more information).

#### IV. Summary of Significant Changes Following Proposal and Rationale

The following sections summarize the significant changes made to the proposed BSCP Manufacturing NESHAP and Clay Ceramics Manufacturing NESHAP, including the rationale for those changes, to respond to public comments and to correct technical inconsistencies or editorial errors in the proposal. A detailed discussion of these and other public comments, as well as other changes not discussed in this section, can be found in the response-to-comments documents, available in Docket ID No. EPA–HQ–OAR–2013–0291 for BSCP Manufacturing and Docket ID No. EPA–HQ–OAR–2013–0290 for Clay Ceramics Manufacturing. All changes to the final rules, including the significant changes discussed in this section and all other changes not discussed in this section, can also be found in the redline comparison of the proposed and final regulatory text, available in Docket ID No. EPA–HQ–OAR–2013–0291 for BSCP Manufacturing and Docket ID No. EPA–HQ–OAR–2013–0290 for Clay Ceramics Manufacturing.

##### A. What are the significant changes since proposal for the BSCP Manufacturing NESHAP?

###### 1. Changes to the Data Set

Following proposal, the EPA learned that two of the facilities in the inventory at proposal were closed and the kilns were demolished. In addition, the EPA learned that two of the synthetic area sources in the inventory at proposal were actually true area sources. These facilities were removed from the master inventory, and the test data from kilns at two of these facilities were also removed from the data set. The EPA learned that a new tunnel kiln had been constructed at a new facility, and that new facility was added to the inventory. The EPA also received additional HF,

HCl, and PM test data for three kilns, which was added into the data set.

In addition, the EPA examined the PM test data more closely and found that a number of the EPA Method 5 test runs had probe or filter temperatures outside of the range of acceptable values. EPA Method 5 specifies that the temperature should be maintained at  $248 \pm 25$  degrees Fahrenheit ( $^{\circ}\text{F}$ ) (*i.e.*, between 223 and 273  $^{\circ}\text{F}$ ). Test runs with temperatures outside that range were removed from the data set. (See the memorandum “Test Data Used in BSCP Manufacturing Final Rule” in Docket ID No. EPA–HQ–OAR–2013–0291 for more information on this analysis.)

Several public commenters stated that the concentration limits for PM and Hg should not be corrected to 7-percent  $\text{O}_2$  because BSCP kilns operate with a higher  $\text{O}_2$  content; one commenter suggested that the EPA use data corrected to 17-percent  $\text{O}_2$  instead. The EPA evaluated this comment and agrees that 17-percent  $\text{O}_2$  is more representative of BSCP kiln operations. Specifically, the EPA evaluated the  $\text{O}_2$  content of the run-by-run datasets of PM and Hg for BSCP tunnel kilns and found that for the PM data set, the oxygen content ranged from 9.5 to 20.5 percent, with an average of 16.8 and a mode of 17 when evaluating the run-by-run  $\text{O}_2$  values rounded to whole numbers. For the Hg data set, the oxygen content ranged from 13.1 to 19.5 percent, with an average of 17.2 and a mode of 17 when evaluating the run-by-run  $\text{O}_2$  values rounded to whole numbers. The EPA agrees that correcting concentration data to 17-percent  $\text{O}_2$  rather than 7-percent, as proposed, provides more representative values of kilns' operating conditions and would not artificially inflate the values. Therefore, the EPA recalculated the oxygen-corrected PM and Hg test runs to be corrected to 17-percent instead of 7-percent  $\text{O}_2$ .

###### 2. Changes to the MACT Floor Pool and Calculations

At proposal, the MACT floors for PM as a surrogate for total non-Hg HAP metals were based on kilns with FF-based APCD, as the EPA considered those to be the best performing sources in the industry. However, as noted in section IV.A.1 of this preamble, the EPA after proposal examined the PM test data in an effort to insure that the data were valid. We found a number of the EPA Method 5 test runs had probe or filter temperatures outside of the range of acceptable values. These out-of-range temperatures invalidated the test runs, and in some cases, invalidated entire PM tests, reducing the set of valid, available test data. Some of the PM test

data removed from the data set were for kilns controlled with a DIFF. As a result, the EPA no longer has data on all the kilns with a FF-based APCD in the industry, which undercuts one of the bases for EPA's proposal to use the best performing FF-based kilns to set a MACT floor based on 12 percent of the kilns in the entire category.

In addition, at proposal the EPA requested more data to further substantiate that kilns with FF-based APCD actually represented the best performing sources in terms of PM emissions. For example, there were some data in the record at the time of the proposal suggesting that in some cases, uncontrolled kilns actually had emissions below the PM emissions of some kilns with FF-based APCD, which is contrary to what we would expect. The EPA requested information to explain these anomalies. However, information was not received during the comment period sufficient to explain why some kilns without FF-based APCD emitted at levels as low as or lower than some kilns with FF-based APCD.

For this reason, and because some of the emissions data on DIFF-controlled kilns had to be removed from the data pool as discussed above, the record does not support the conclusion that we have PM emissions data on all the best performing kilns in the industry. Given that, we are instead basing the PM MACT floor on 12 percent of the kilns for which we have emissions data. Therefore, the final MACT floor pools for PM as a surrogate for total non-Hg HAP metals are not based on the top 12 percent of the kilns in the industry (*i.e.*, the 27 best performing sources). Instead, the final MACT floor limits are based on the top 12 percent of the sources for which we have emissions data available in each of the kiln size subcategories, consistent with the approach described for the proposed alternate non-Hg HAP metals standards in section IV.Q.1 of the preamble to the proposed rule (79 FR 75649).

In addition, in response to public comments received on the proposed rule, and consistent with the proposed alternate approach in section IV.Q.1 of the preamble to the proposed rule, the EPA has decided to exercise its discretion to subcategorize for emissions of PM based on kiln size in the final rule. Section 112(d)(1) of the CAA allows the EPA to promulgate emission standards for either categories or subcategories of sources. Section IV.C of the preamble to the proposed rule (79 FR 75633) described the EPA's assessment of tunnel kiln size subcategories. When the EPA recalculated the MACT floor pools for

PM as a surrogate for total non-Hg HAP metals as described in the previous paragraph, the EPA evaluated subcategorizing by kiln size and determined it is appropriate to exercise its discretion to subcategorize in this case. This subcategorization provides additional flexibility for small tunnel kilns, many of which are operated by small businesses. Therefore, the final MACT floor limits for PM as a surrogate for total non-Hg HAP metals are based on the best performing 12 percent of the sources in each of the kiln size subcategories with valid test data (*i.e.*, 12 percent of the data available).

The EPA also proposed two alternative equivalent limits, calculated based on the same best performing sources ranked by lb/ton, then using those units' concentration or lb/hr data to calculate the floor. During the public comment period, the EPA received comments that each alternative limit should be calculated according to a separate ranking based on the specific unit of measure. Upon further analysis of the data sets for each unit of measure, the EPA has found that there are some differences in the top ranked sources between each unit of measure data set and thus finds the alternative limits expressed on their own unit of measure data set ranking to be the most indicative of that data set's MACT floor. Therefore, the EPA re-ranked the data for each unit of measurement in each kiln size subcategory separately. The final alternative equivalent limits are based on the top 12 percent of the data available in each subcategory according to these revised rankings. In other words, the concentration floor is based on the ranking of the concentration data, and the lb/hr floor is based on the ranking of the lb/hr data. Each floor is based on the best performing units for that unit of measurement. In addition, the final lb/hr non-Hg HAP metals alternative limit is based on a ranking of the non-Hg HAP metals data rather than the use of conversion factors applied to the PM lb/ton floor limit, as was done at proposal.

### 3. Variability Calculation Based on Hg Raw Material Data

At proposal, the EPA developed Hg MACT floors based on the best performing 12 percent of sources (*i.e.*, the lowest emitting sources of Hg emissions from test data). However, commenters identified that the Hg comes from the raw materials used and the Hg content can vary by location, even within the same quarry. The EPA did not account for this inherent variability at proposal. The Brick Industry Association (BIA) coordinated

with several BSCP facilities to test the Hg content of the raw materials used and provided the data to the EPA. The EPA mapped the facilities and quarry locations provided by BIA to identify two distinct quarry locations, an Oklahoma deposit and an Ohio deposit, for use in the development of a Hg raw material variability factor. The data from these two deposit locations were incorporated into the upper prediction limit (UPL) equation. Please see "Mercury Content of Oklahoma and Ohio Shale Deposits Supplying the Brick Industry" and "Final Maximum Achievable Control Technology (MACT) Floor Analysis for Brick and Structural Clay Products" in Docket ID No. EPA-HQ-OAR-2013-0291 for more information about the data and variability factor.

### 4. Startup and Shutdown Procedures

The EPA proposed work practice standards during periods of startup and shutdown for tunnel kilns with and without APCD. These standards set a minimum temperature above which the exhaust must be vented through an APCD (if applicable) and below which no product could be introduced to the kiln (400 °F for startup and 300 °F for shutdown). Industry commenters indicated that the exhaust of some kilns never reaches the specific temperatures proposed by the EPA, and that some product must be introduced to the kiln during startup to heat the kiln enough for full production. The EPA evaluated these comments and agrees that the proposed standards do not actually represent the work practices representative of the best performing kilns. The intent of the proposed standards was to represent work practices of the best performing kilns to minimize emissions by limiting the amount of brick being fired before the kiln reaches full production and limiting the amount of time the exhaust is not being routed to the APCD, if applicable. As noted at proposal, the standards were based on information received through the 2010 EPA survey. The EPA received additional information following proposal on the procedures used during periods of startup and shutdown for BSCP tunnel kilns that are more representative of the best performing kilns.

Therefore, the EPA is finalizing work practice standards for periods of startup and shutdown that are based upon the same principles as the proposed standards but are representative of how kilns actually perform during startup. Instead of defining the minimum inlet APCD temperature as 400 °F, the EPA is requiring the owner or operator to

determine the minimum inlet temperature for each APCD. If a kiln does not have an APCD, the owner or operator is required to determine the product-specific kiln temperature profile that must be achieved before the kiln can reach full production. In addition, instead of specifying that no product can be introduced to the kiln during startup, the EPA is requiring the owner or operator to determine the production rate needed to start up the kiln. The final startup standards specify that this startup production rate cannot be exceeded until the kiln exhaust reaches the APCD minimum inlet temperature or the product-specific kiln temperature profile. The final shutdown standards specify that no additional product can be introduced once the kiln exhaust falls below the APCD minimum inlet temperature or the product-specific kiln temperature profile.

*B. What are the significant changes since proposal for the Clay Ceramics Manufacturing NESHAP?*

1. Changes to the Data Set

After proposal, a public commenter identified a transcription error in the production rate for the PM and Hg stack tests for one floor tile roller kiln. The production rate was corrected, and the PM and Hg lb/ton values were recalculated. In addition, the EPA examined the PM test data more closely and found that a number of the EPA Method 5 test runs had probe or filter temperatures outside of the range of acceptable values. EPA Method 5 specifies that the temperature should be maintained at 248 ± 25 °F (i.e., between 223 and 273 °F). Test runs with temperatures outside that range were removed from the data set. (See the memorandum “Test Data Used in Clay Ceramics Manufacturing Final Rule” in Docket ID No. EPA-HQ-OAR-2013-0290 for more information on this analysis.)

During the public comment period, the sanitaryware manufacturing

company that provided all of the data used for the sanitaryware tunnel kiln MACT floors clarified that the production rates they provided in their CAA section 114 survey response are in terms of “greenware fired” into the kiln rather than “fired product” coming out of the kiln (as requested in the section 114 survey). Therefore, to be consistent with the data, the final emission limits for PM as a surrogate for non-Hg HAP metals and Hg from sanitaryware tunnel kilns are in terms of lb/ton of greenware fired rather than lb/ton of product fired (as proposed).

Finally, in response to comments requesting a change in the format of the emission limits for dioxins/furans, the EPA recalculated the emissions for each test run in units of ng/kg of throughput (specifically, “fired product” for ceramic tile roller kilns, “greenware fired” for sanitaryware tunnel kilns, and “throughput processed” for ceramic tile press dryers and spray dryers). The MACT floors were then recalculated using those data, and the final emission limits for dioxins/furans for clay ceramics sources are in units of ng/kg rather than concentration as proposed.

2. Startup and Shutdown Procedures

The EPA proposed work practice standards during periods of startup and shutdown for ceramic tile roller kilns, floor tile press dryers, ceramic tile spray dryers and sanitaryware tunnel kilns with and without APCD. These standards set a minimum temperature above which the exhaust must be vented through an APCD (if applicable) and below which no product could be introduced to the kiln or dryer (400 °F for startup and 300 °F for shutdown). One industry commenter indicated that the exhaust of some dryers never reach the specific temperatures proposed by the EPA. The EPA evaluated the comment and agrees that the proposed standards are not actually representative of the best performing dryers.

Therefore, the EPA is finalizing work practice standards for periods of startup and shutdown that are based upon the same principles as the proposed standards but more accurately reflect the best performing sources. Instead of defining the minimum inlet APCD temperature as 400 °F, the EPA is requiring the owner or operator to determine the minimum inlet temperature for each APCD. If a kiln or dryer does not have an APCD, the owner or operator is required to determine the product-specific kiln or dryer temperature profile that must be achieved before the kiln or dryer can reach full production. In addition, instead of specifying that no product can be introduced to the kiln or dryer, the EPA is requiring the owner or operator to determine the production rate needed to start up the kiln or dryer. The final startup standards specify that this startup production rate cannot be exceeded until the kiln or dryer exhaust reaches the APCD minimum inlet temperature or the product-specific kiln or dryer temperature profile. The final shutdown standards specify that no additional throughput can be introduced once the kiln or dryer exhaust falls below the APCD minimum inlet temperature or the product-specific kiln or dryer temperature profile.

*C. What are the changes to monitoring requirements since proposal?*

A number of changes have been made to the monitoring requirements for the BSCP and Clay Ceramics Manufacturing NESHAP in response to comments on the proposed rule. These changes are summarized in Table 6 of this preamble. Further details about the basis for these changes are provided in the response-to-comments documents for the BSCP Manufacturing NESHAP and the Clay Ceramics Manufacturing NESHAP, available in Docket Nos. EPA-HQ-OAR-2013-0290 (Clay Ceramics Manufacturing) and EPA-HQ-OAR-2013-0291 (BSCP Manufacturing).

TABLE 6—SUMMARY OF CHANGES TO MONITORING REQUIREMENTS SINCE PROPOSAL

Sources	Monitoring requirements	
	Proposal	Promulgation
BSCP or clay ceramics kilns equipped with a wet scrubber.	To demonstrate compliance with acid gas standard: <ul style="list-style-type: none"> <li>• Monitor scrubber liquid pH .....</li> <li>• Monitor scrubber chemical feed rate (if applicable).</li> <li>• Maintain at or above average pH/feed rate during acid gas test.</li> </ul>	To demonstrate compliance with acid gas standard: <ul style="list-style-type: none"> <li>• Monitor scrubber liquid pH</li> <li>• Maintain at or above highest average ph during acid gas test</li> </ul>

TABLE 6—SUMMARY OF CHANGES TO MONITORING REQUIREMENTS SINCE PROPOSAL—Continued

Sources	Monitoring requirements	
	Proposal	Promulgation
BSCP kilns with no add-on control .....	To demonstrate compliance with non-Hg HAP metals standard: <ul style="list-style-type: none"> <li>• Monitor scrubber pressure drop. ....</li> <li>• Maintain at or above average pressure drop during PM/non-Hg HAP metals test..</li> </ul>	To demonstrate compliance with non-Hg HAP metals and acid gas standards: <ul style="list-style-type: none"> <li>• Monitor scrubber liquid flow rate.</li> <li>• Maintain at or above highest average flow rate during PM/non-Hg HAP metals and acid gas tests.</li> </ul>
	To demonstrate compliance with non-Hg HAP metals and acid gas standards: <ul style="list-style-type: none"> <li>• Monitor scrubber liquid flow rate. ....</li> <li>• Maintain at or above average flow rate during PM/non-Hg HAP metals and acid gas tests..</li> </ul>	
	To demonstrate compliance with non-Hg HAP metals standard: <ul style="list-style-type: none"> <li>• Perform daily, 15-minute VE observations.</li> <li>• If VE are observed, initiate and complete corrective actions..</li> </ul>	To demonstrate compliance with non-Hg HAP metals standard: <ul style="list-style-type: none"> <li>• Perform daily, 15-minute VE observations</li> <li>• If VE are observed, promptly conduct an opacity test</li> <li>• If opacity greater than 10% are observed, initiate and complete corrective actions</li> </ul>
Clay ceramics kilns with no add-on control, or intending to comply with dioxin/furan standard without an ACI system.	To demonstrate compliance with dioxins/furans standard: <ul style="list-style-type: none"> <li>• Monitor kiln operating temperature. ....</li> <li>• Maintain at or above average operating temperature during dioxin/furan test..</li> </ul>	To demonstrate compliance with dioxins/furans standard: <ul style="list-style-type: none"> <li>• Monitor kiln stack temperature</li> <li>• Maintain at or below highest stack temperature during dioxin/furan test</li> </ul>

**V. Summary of Significant Comments and Responses**

The EPA received a total of 52 public comment letters on the proposed BSCP Manufacturing NESHAP. (See Docket ID No. EPA-HQ-OAR-2013-0291 for the complete public comments.) The EPA received a total of seven public comment letters on the proposed Clay Ceramics Manufacturing NESHAP. (See Docket ID No. EPA-HQ-OAR-2013-0290 for the complete public comments.) The following sections summarize the major public comments received on the proposal and present the EPA’s responses to those comments.

**A. Health-Based Standards**

*Comment:* Two commenters disagreed with setting standards under CAA section 112(d)(4) for emissions of HCl, HF, and Cl<sub>2</sub> from new and existing BSCP and clay ceramics sources. One commenter questioned whether the EPA has the authority to set CAA section 112(d)(4) standards for these acid gases. The commenter asserted that it would be arbitrary and capricious for the EPA to set risk-based standards for these pollutants when the EPA previously decided not to set CAA section 112(d)(4) standards for HCl, HF, and Cl<sub>2</sub> in air toxics rulemakings for industrial boilers and power plants. For power plants, the EPA stated that the agency “does not have sufficient information to establish CAA section 112(d)(4) health-based emission standards and we did not receive such data during the comment

period.”<sup>1</sup> The commenter noted that the EPA reached a similar conclusion with respect to industrial boilers, declining to set risk-based standards because of a lack of information on emissions.<sup>2</sup> The commenter asserted that the health and scientific data regarding emissions of acid gases from BSCP and clay ceramics plants similarly fail to provide justification for setting HBEL for these pollutants. The commenter asserted the EPA must instead set MACT standards.

Similarly, the second commenter expressed concern over using CAA section 112(d)(4) and health-based risk assessment for setting the HCl, HF and Cl<sub>2</sub> standards for BSCP Manufacturing and Clay Ceramics Manufacturing. The commenter noted that this would be the first time the EPA used the health-based risk assessment approach under CAA section 112(d)(4) to set emission standards for HF and Cl<sub>2</sub>; although the EPA has used this approach in the past to establish health-based standards for other source categories, it was restricted to “HCl emissions for discrete units within the facility” (79 FR 75639).

The commenter supported focusing on pollutants that pose the greatest risks but expressed concern that the EPA has

not adequately established that the approaches used are appropriate. The commenter asserted that the EPA’s approach represented a far-reaching and significant change in the manner in which MACT standards are established under CAA section 112(d) and that it was inappropriate for the EPA to propose such changes in a rulemaking for individual source categories instead of discussing the approach with all affected parties. The commenter noted that Congress established section 112 of the CAA to rely on a technology-based approach to avoid the gridlock of the unsuccessful risk-based methods used before the adoption of the 1990 CAA Amendments. Accordingly, while the CAA includes language under section 112(d)(4) allowing the use of risk in the establishment of MACT, it should be used only under limited and very specific circumstances, and the commenter stated that the EPA’s proposal did not adequately make the case for the use of CAA section 112(d)(4).

Conversely, two other commenters stated that the EPA has clear legal authority to set HBEL and ample justification to do so for the BSCP source category. The commenters stated that under the terms of this provision, the EPA may set an emission standard at a level higher than would be required by CAA section 112(d)(4), provided that: (1) The pollutant(s) being regulated is a threshold pollutant and (2) the standard provides an ample margin of safety. The

<sup>1</sup> “Responses to Public Comments on National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units.” Docket Item No. EPA-HQ-OAR-2009-0234-20126.

<sup>2</sup> National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters, 75 FR 32006, 32031 (June 4, 2010).



commenters stated that both of these criteria are met in this case.

The commenters asserted that the proposed standard is consistent with Congress's expectations regarding the implementation of CAA section 112(d)(4). According to the Senate report accompanying the legislation, "For some pollutants a MACT emission limitation may be far more stringent than is necessary to protect public health and the environment" and in such situations, "[t]o avoid expenditures by regulated entities which secure no public health or environmental benefit, the Administrator is given discretionary authority to consider the evidence for a health threshold higher than MACT at the time the standard is under review."<sup>3</sup> The commenters stated that for this rulemaking, MACT would result in emission standards that are far more stringent than are needed to protect health and the environment and asserted that Congress enacted CAA section 112(d)(4) to allow emission standards to be tailored to protect public health without imposing unreasonable and unnecessary standards on affected sources.

*Response:* The EPA disagrees with the commenters that we do not have the authority to establish CAA section 112(d)(4) standards in this rulemaking. The EPA also disagrees that the decision to establish CAA section 112(d)(4) standards is inconsistent with our decisions on other rulemakings. The commenters' more detailed arguments and the EPA's responses are provided in the remainder of this section.

#### 1. Health Thresholds

*Comment:* One commenter stated that a pollutant is not a threshold pollutant under CAA section 112(d)(4) unless the EPA establishes that it cannot cause cancer at any level of exposure. The commenter asserted that HCl, HF, and Cl<sub>2</sub> do not have already-established safe health thresholds and the EPA's proposed standards would not provide "an ample margin of safety."

Conversely, two commenters agreed with the EPA that the available health data indicate that HCl, HF, and Cl<sub>2</sub> are all threshold pollutants. The commenters stated that the data show that each of these pollutants has a discernible exposure threshold below which adverse human health effects are not expected to occur; in addition, none of the available data suggest that these pollutants reasonably should be expected to act as a carcinogen or

mutagen, or exhibit a mode of action that would result in non-threshold effects.

*Response:* The EPA disagrees with the first commenter regarding HCl, HF and Cl<sub>2</sub> not having thresholds accepted by the scientific community, and we acknowledge the support of the other two commenters. The EPA's conclusion that HCl, HF and Cl<sub>2</sub> are threshold pollutants is based on the best available toxicity database considered in hazard identification and dose response assessments. There is agreement on using a similar threshold approach for these chemicals across agencies, *i.e.*, the EPA's Integrated Risk Information System (IRIS) Program, Agency for Toxic Substances and Disease Registry (ATSDR) and the California Environmental Protection Agency (CalEPA). The toxicity assessments, which include noncancer and/or cancer toxicity assessments, provided by these authoritative bodies are widely vetted through the scientific community and undergo rigorous peer review processes before they are published. In addition, the Science Advisory Board (SAB) has endorsed the use of the reference values derived by these sources to support the EPA's risk assessments in the residual risk and technology review (RTR) program.

Specifically, none of the compounds discussed here has been classified as a carcinogen or as "suggestive of the potential to be carcinogenic," individually or in combination, by existing authoritative bodies, including EPA, CalEPA, International Agency for Research on Cancer (IARC), Organisation for Economic Co-operation and Development (OECD), and the European Community. In light of the absence of evidence of carcinogenic risk for any of these pollutants, and the evidence of an existing threshold below which HCl, HF and Cl<sub>2</sub> are not expected to cause adverse effects, the EPA considers it appropriate to set health threshold standards under CAA section 112(d)(4) for these pollutants. The existing health effects evidence on HCl, HF and Cl<sub>2</sub> that provide support for this determination is described below.

##### Potential health effects of HCl:

- There are limited studies on the carcinogenic potential of HCl in humans. The occupational data are limited to a couple of studies (Steenland *et al.*, 1988, Beaumont *et al.*, 1986)<sup>4,5</sup>

<sup>4</sup> Steenland, K., T. Schnorr, J. Beaumont, W. Halperin, T. Bloom. 1988. Incidence of laryngeal cancer and exposure to acid mists. *Br. J. of Ind. Med.* 45: 766-776.

<sup>5</sup> Beaumont, J.J., J. Leveton, K. Knox, T. Bloom, T. McQuiston, M Young, R. Goldsmith, N.K. Steenland, D. Brown, W.E. Halperin. 1987. Lung

where the subjects were exposed to a mixture of acid gases (mainly sulfuric acid) and other chemicals (including metals) that may have contained HCl. These studies failed to separate potential exposure of HCl from exposure to other substances shown to have carcinogenic activity and are therefore not appropriate to evaluate the carcinogenic potential of HCl. Another occupational study failed to show evidence of association between exposure to HCl and lung cancer among chemical manufacturing plant employees showing that there is no evidence that HCl is a human carcinogen.<sup>6</sup>

- Consistent with the human data, chronic inhalation studies in animals have reported no carcinogenic responses after chronic exposure to HCl (Albert *et al.*, 1982; Sellakumar *et al.*, 1985).<sup>7,8</sup>

- Hydrogen chloride has not been demonstrated to be genotoxic. The genotoxicity database consists of two studies showing false positive results potentially associated with low pH in the test system (Morita *et al.*, 1992; Cifone *et al.*, 1987).<sup>9,10</sup>

- Chronic exposure to HCl at concentrations below the current IRIS reference concentration (RfC) are not expected to cause adverse effects.

##### Potential health effects of HF:

- There are a limited number of studies investigating the carcinogenic potential of HF. These studies are unreliable on the issue of possible carcinogenicity of HF and/or fluorides, in general, because of many confounding factors (*e.g.*, exposure to multiple unknown chemicals and smoking habits not accounted for) and because no breakdown was done by type of fluoride exposure.<sup>11</sup>

cancer mortality in workers exposed to sulfuric acid mist and other acid mists. *JNCL* 79: 911-921.

<sup>6</sup> Bond G.G., Flores G.H., Stafford B.A., Olsen G.W. Lung cancer and hydrogen chloride exposure: results from a nested case-control study of chemical workers. 1991. *J Occup Med*; 33(9), 958-61.

<sup>7</sup> Albert, R.E., A.R. Sellakumar, S. Laskin, M. Kuschner, N. Nelson and C.A. Snyder. 1982. Gaseous formaldehyde and hydrogen chloride induction of nasal cancer in rats. *J. Natl. Cancer Inst.* 68(4): 597-603.

<sup>8</sup> Sellakumar, A.R., C.A. Snyder, J.J. Solomon and R.E. Albert. 1985. Carcinogenicity for formaldehyde and hydrogen chloride in rats. *Toxicol. Appl. Pharmacol.* 81: 401-406.

<sup>9</sup> Morita, T., T. Nagaki, I. Fukuda, K. Okumura. 1992. Clastogenicity of low pH to various cultured mammalian cells. *Mutat. Res.* 268: 297-305.

<sup>10</sup> Cifone, M.A., B. Myhr, A. Eiche, G. Bolcsfoldi. 1987. Effect of pH shifts on the mutant frequency at the thymidine kinase locus in mouse lymphoma L5178Y TK<sup>-/-</sup> cells. *Mutat. Res.* 189: 39-46.

<sup>11</sup> U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. Toxicological Profile for Fluorides, Hydrogen Fluoride and Fluorine. 2003. Available at <http://www.atsdr.cdc.gov/toxprofiles/tp11.pdf>.

<sup>3</sup> S. Rep. No. 101-228, 101st Cong. 1st sess. at 171.

- Chronic exposure at or below the current CalEPA reference exposure level (REL) is not expected to cause adverse effects.

Potential health effects of Cl<sub>2</sub>:

- The existing studies of workers in the chemical industry have not found any evidence that Cl<sub>2</sub> is carcinogenic.

- Chronic bioassays in rodents and long-term studies in non-human primates have shown no evidence for carcinogenicity in respiratory tract as target tissue or other tissues.

- Chronic exposure to Cl<sub>2</sub> at concentrations below the current ATSDR minimal risk level (MRL) are not expected to cause adverse effects.

We disagree with the comment that the EPA's proposed HBEL does not provide an ample margin of safety, for the following reasons.

First, the limit is based on the facility in the source category with the highest potential exposure to nearby residents. The HBEL at this single facility reflects a ratio of exposure concentration over the reference value of up to 1 (at an exposure concentration below the RfC is considered to be health protective). As such, exposures will not exceed the established health threshold at this facility. In addition, the exposure estimate used to set the limit is very health protective in that it assumes constant exposure for 70 years. Actual exposures from emissions from this facility are expected to be lower (*i.e.*, because persons will spend time away from home). This conservative exposure scenario is consistent with the "ample margin of safety" requirement in CAA section 112(d)(4).

Second, the ratios at the other facilities (not the highest facility noted above) from this source category are lower and in most cases significantly lower, with approximately 90 percent of these facilities having a ratio of 0.5 or less, which provides a further increased margin of safety beyond the ample margin of safety established at the facility with the highest potential exposure.

*Comment:* One commenter stated that, according to the EPA, an RfC is merely "an estimate (with uncertainty spanning perhaps an order of magnitude)" of an exposure that is "likely to be" without health risks.<sup>12</sup> By definition, this "estimate" is not by itself a "safe threshold" of exposure that "presents no risk" of adverse health effects. The commenter stated the EPA cannot lawfully use a pollutant's RfC as a default "safe threshold" under CAA

section 112(d)(4) because an RfC does not pose "no" health risks, as the commenter asserted the CAA requires.

The commenter stated that the EPA is authorized to set risk-based standards only where it has direct evidence of the level at which there are no adverse effects observed and that proceeding with HBEL without a no observed adverse effect level (NOAEL) is unlawful. Another commenter stated the use of health-based standards should only be considered for HAP that have been thoroughly evaluated by the EPA and are contained in the IRIS database with a high level of confidence in the RfC. With respect to HCl, the IRIS confidence levels are "Low" for the inhalation RfC. In "Carcinogenicity Assessment for Lifetime Exposure," IRIS states, "This substance/agent has not undergone a complete evaluation and determination under the EPA's IRIS program for evidence of human carcinogenic potential."<sup>13</sup> In the proposal, the EPA acknowledged that "[t]he EPA has not classified HCl for carcinogenicity" and "[l]ittle research has been conducted on its carcinogenicity" (79 FR 75639).

The commenter also stated that IARC concluded that "[t]here is inadequate evidence for the carcinogenicity in humans of hydrochloric acid," that "[t]here is inadequate evidence for the carcinogenicity in experimental animals of hydrochloric acid," and that HCl "is not classifiable as to its carcinogenicity to humans."<sup>14</sup> The commenter stated that the EPA did not identify any evidence that HCl is not carcinogenic and noted that the only study the EPA referenced is "one occupational study" that "found no evidence of carcinogenicity" (79 FR 75639). Because the EPA did not provide a citation for the study or otherwise identify it or discuss it, the public are unable to adequately comment on it.

*Response:* The EPA's risk assessments are supported by the best available toxicity assessments from authoritative bodies including the EPA's IRIS Program, ATSDR and CalEPA. The SAB has endorsed the use of the reference values derived by these sources to support EPA's risk assessments in the RTR program. These authoritative bodies derive health protective reference values at or below which no adverse effects are expected to occur. As mentioned previously in this section, the toxicity assessments, which include

noncancer and/or cancer toxicity assessments, provided by these authoritative bodies are widely vetted through the scientific community and undergo rigorous peer review processes before they are published.

The commenter stated that there is not a NOAEL and that based on that, the EPA cannot set a HBEL for HCl. The EPA toxicity assessments consider the entire toxicity database for specific chemicals and are conducted following well-established EPA guidance on how to assess potential hazard of a chemical and conduct dose response assessments. These assessments include the derivation of an RfC, which is likely to be without appreciable risk of adverse health effects to the human population (including susceptible subgroups and all life stages) over a lifetime. According to EPA guidelines, RfCs can be derived from a NOAEL, lowest observed adverse effect level (LOAEL) or benchmark dose, with uncertainty factors applied to reflect the limitations of the data used. In particular for HCl, the point of departure for the RfC (15 milligrams per cubic meter (mg/m<sup>3</sup>)) was selected from chronic inhalation studies in rodents and was adjusted to reflect a lifetime of exposure (2.7 mg/m<sup>3</sup>) and extrapolated to a human equivalent concentration (6.1 mg/m<sup>3</sup>) based on differences in the effects of a gas in the respiratory system between rats and humans. Uncertainty factors (total of 300, yielding an RfC of 0.02 mg/m<sup>3</sup>) were applied to account for interspecies differences, intraspecies extrapolation and extrapolation from a LOAEL to NOAEL. It is important to note that in the IRIS assessment for HCl it is stated that a reasonable estimate of the NOAEL in humans is in the range of 0.3–3 mg/m<sup>3</sup>. This estimate resulted from an expert review workshop and is based on examination of the HCl literature, a comparison with sulfuric acid toxicity, and the judgment of those in attendance at the review workshop. In addition, this value is generally consistent with identified NOAELs in subchronic animal studies (OECD, 2002). Based on this information, we are confident that the IRIS HCl RfC represents a conservative health protective benchmark below which adverse health effects are not expected to occur.

As part of the risk analysis conducted to support this rule, the EPA thoroughly evaluated all the available and relevant scientific evidence on HCl (discussed previously in this section) and concluded that there is no evidence that HCl is a carcinogen and that this information is sufficient for this regulatory determination. The 2002

<sup>13</sup> U.S. EPA, Integrated Risk Information System—Hydrogen chloride. <http://www.epa.gov/iris/subst/0396.htm#coninhal>.

<sup>14</sup> IARC, Hydrochloric Acid (Monograph), available at <http://monographs.iarc.fr/ENG/Monographs/vol54/mono54-8.pdf>.

<sup>12</sup> U.S. EPA, Glossary, <http://www.epa.gov/risk-assessment/glossary.htm> (last updated Apr. 28, 2014).

OECD assessment of HCl drew similar conclusions:

For genetic toxicity, a negative result has been shown in the Ames test. A positive result in a chromosome aberration test using Hamster ovary cells is considered to be an artifact due to the low pH. For carcinogenicity, no pre-neoplastic or neoplastic nasal lesions were observed in a 128-week inhalation study with SD male rats at 10 ppm hydrogen chloride gas. No evidence of treatment related carcinogenicity was observed in other animal studies performed by inhalation, oral or dermal administration. In humans, no association between hydrogen chloride exposure and tumor incidence was observed.<sup>15</sup>

Additionally, the EPA conducted a screening level literature review in 2003 and did not identify any critical studies that would change the conclusions in the 1995 HCl IRIS assessment. Based on the information available, the EPA concludes that this information is sufficient to support setting an HBEL under CAA section 112(d)(4) for HCl.

*Comment:* One commenter stated that the EPA proposed to base the HCl emission standards on the HCl RfC and argued it is unlawful to do so where the EPA has “low confidence” in the RfC. The commenter stated that it is arbitrary to claim there is an established, safe health threshold based on a reference value in which the EPA has low confidence. According to the commenter, having low confidence in the RfC is the same as admitting that the EPA has “low confidence” in the proposed emission standards. The fact that the EPA was unable to determine a no-effect level in a robust and reliable scientific study demonstrates concern that chronic exposure to even very low levels of HCl can compromise health, especially in sensitive subpopulations. Therefore, the EPA cannot state that HCl presents no risk of adverse health effects.

The commenter stated that the EPA used a non-cancer health threshold for HCl based on a chronic inhalation study on rats.<sup>16</sup> The EPA has determined the RfC to be 0.02 mg/m<sup>3</sup> (0.0134 part per million (ppm)), based on rat studies by Albert, *et al.*, demonstrating hyperplasia of the nasal mucosa (the protective cell lining of the nasal tract and cavities), larynx, and trachea.<sup>17</sup> The commenter

asserted that because these rat studies failed to identify a NOAEL, the EPA based the RfC on a LOAEL (*i.e.*, the lowest dose in the study that induced a measurable adverse health effect in treated animals). The commenter asserted that CAA section 112(d)(4) does not permit risk-based standards where a NOAEL has not been determined; at a minimum, Congress required that a threshold be based on the “‘no observable [adverse] effects level’ (NOAEL) below which human exposure is presumably ‘safe.’”<sup>18</sup> The EPA has similarly recognized that “the legislative history of CAA section 112(d)(4) indicates that a health-based emission limit under CAA section 112(d)(4) should be set at the level at which no observable effects occur” (79 FR 75642). The commenter stated that, if there is no established non-zero threshold level at which it has been shown that the pollutant has no deleterious health effects, then the EPA cannot be certain that exposure to the pollutant at a given level presents no harm. The commenter stated that without a NOAEL, no established threshold can exist, and the EPA does not have the authority under CAA section 112(d)(4) to set an HBEL for HCl.

*Response:* The EPA’s chemical-specific toxicity assessments are derived using the EPA’s risk assessment guidelines and approaches that are well established and vetted through the scientific community, and follow rigorous peer review processes.<sup>19</sup> The RTR program gives preference to EPA values (*i.e.*, RfCs for noncancer assessments) for use in risk assessments and uses other values, as appropriate, when those values are derived with methods and peer review processes consistent with those followed by the EPA. The approach for selecting appropriate toxicity values for use in the RTR Program has been endorsed by the SAB.<sup>20</sup>

The EPA’s RfCs are assigned confidence levels of high, medium and low based on the completeness of the supporting database. High confidence RfCs are considered less likely to change substantially with the collection of

additional information, while low confidence RfCs are recognized as being based on less complete data and so may be subject to change if additional data is developed.<sup>21</sup> It is important to note that a “low confidence” label does not indicate that the EPA believes that the RfC is unreliable. For a given chemical, if there are not adequate or appropriate data with which to derive an RfC, one is not calculated. All RfCs, even those with low confidence, are appropriate for regulatory use.

We disagree with the comment that without a NOAEL, no established threshold can exist. The EPA toxicity assessments for specific chemicals are conducted using well-established EPA guidance on how to assess potential hazard of chemicals and how to conduct dose response assessments to arrive at a chemical concentration below which we do not expect adverse effects to occur (*i.e.*, threshold). These assessments include the derivation of a RfC which is likely to be without appreciable risk of adverse health effects to the human population (including susceptible subgroups and all life stages [*e.g.*, children]) over a lifetime. According to EPA guidelines, RfCs can be derived from a NOAEL, LOAEL or benchmark dose, with uncertainty factors applied to account for relevant extrapolations, including extrapolation from LOAEL to NOAEL, and to reflect additional limitations of the data used.<sup>22 23</sup>

*Comment:* One commenter stated that the studies the EPA relied upon only investigated respiratory effects and did not consider other ways HCl could cause harm. The commenter noted the EPA has acknowledged that the RfC is an “inhalation RfC” and represents the health risk and toxicity associated with the inhalation pathway of exposure only (75 FR 32031). The commenter stated that the EPA identified no studies that indicate whether exposure to HCl—at 0.02 mg/m<sup>3</sup> or any other concentration—harms other bodily systems.

*Response:* The EPA disagrees with the comment that the agency investigated only respiratory effects and that it did not consider other ways in which HCl can cause harm. In the principal studies

<sup>15</sup> S. Rep. No. 101–228, at 171, 176.

<sup>16</sup> Integrated Risk Information System (IRIS). IRIS Guidance documents available at <http://www.epa.gov/iris/backgrd.html>.

<sup>17</sup> Science Advisory Board. Memorandum to Lisa Jackson, Administrator, U.S. EPA. Review of EPA’s draft entitled, “Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA’s Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing.” May 7, 2010. Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/44B3966E263D943A8525771F00668381/\\$File/EPA-SAB-10-007-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/44B3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf).

<sup>21</sup> U.S. EPA Air: Fate, Exposure, and Risk Analysis Web site. Air Toxics Assessment Reference Library, Volume 1. 2004. Available at [http://www2.epa.gov/sites/production/files/2013-08/documents/volume\\_1\\_reflibrary.pdf](http://www2.epa.gov/sites/production/files/2013-08/documents/volume_1_reflibrary.pdf).

<sup>22</sup> U.S. EPA. 1994. Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry. EPA/600/8-90/066F, Oct 1994. Docket Item No. EPA-HQ-OAR-2013-0291-0160.

<sup>23</sup> U.S. EPA. 2002. A Review of the Reference Dose and Reference Concentration Processes. EPA/630/P-02/002F, Dec 2002.

<sup>15</sup> United Nations Environment Programme 2002, Organisation for Economic Co-operation and Development (OECD), Screening Information Dataset (SIDS) Initial Assessment Report for SIAM 15, Hydrogen Chloride: CAS N°:7647–01–0. October 25, 2002. <http://www.inchem.org/documents/sids/sids/7647010.pdf>.

<sup>16</sup> EPA, Integrated Risk Information System: Hydrogen Chloride.

<sup>17</sup> Albert, R.E., *et al.*, Gaseous formaldehyde and hydrogen chloride induction of nasal cancer in rats, 68(4) J. Natl. Cancer Inst. 597 (1982).

upon which the RfC is based, a complete necropsy was performed on all animals. Histologic sections were prepared from the nasal cavity, lung, trachea, larynx, liver, kidneys, testes, and other organs where gross pathological signs were present. Due to the reactive nature of HCl, however, portal of entry effects are anticipated to occur first and at lower exposure concentrations. The IRIS assessment<sup>24</sup> for HCl included a comprehensive review of all the available toxicity data for HCl. No effects are expected to occur at exposures of HCl at or below the level of the RfC.

*Comment:* One commenter stated that the RfC is an inadequate basis for establishing a threshold because it “did not reflect any potential cumulative or synergistic effects of an individual’s exposure to multiple HAP or to a combination of HAP and criteria pollutants” and noted that the EPA recognized the potential for cumulative and synergistic effects was important in its consideration of risk-based standards in two recent rulemakings (see 75 FR 32031 and 76 FR 25050).

The commenter stated that there is no “established” threshold at the RfC for HCl, because the CalEPA has determined a lower and more health-protective value than the RfC. The EPA’s chronic inhalation RfC is 0.02 mg/m<sup>3</sup>, while California’s chronic inhalation REL is 0.009 mg/m<sup>3</sup>.<sup>25</sup> The commenter stated that CalEPA’s REL is based on the same science as the IRIS RfC but was developed more recently than the EPA’s RfC, which was last revised in 1995.<sup>26</sup> The REL is “the concentration level at or below which no health effects are anticipated in the general human population,” and the EPA’s process for developing RELs “is similar to that used by EPA to develop IRIS values and incorporates significant external scientific peer review.”<sup>27</sup> The commenter asserted that the EPA and CalEPA disagree about the concentration of HCl exposure at which no health effects are expected and that

the disagreement stems from how to account for uncertainty and variability in interpreting the study results.

The fact that two agencies have determined significantly different “safe” levels, the commenter contended, demonstrates as a matter of law that there is no “established” health threshold for HCl and precludes the EPA from lawfully setting CAA section 112(d)(4) standards for HCl. The commenter stated that the statute requires that a health threshold “has been established” and argued the legislative history indicates Congress intended for CAA section 112(d)(4) limits to be used only where there was a “well-established” level that presents “no risk” of adverse effects and about which there was no “dispute.”<sup>28</sup> The commenter asserted that Congress did not grant the Administrator the authority to establish the threshold itself and that the EPA does not have authority to set CAA section 112(d)(4) standards in situations where there is disagreement among expert agencies as to what the correct health threshold should be.

The commenter asserted that by failing to address the CalEPA REL, the EPA contravened its obligation under administrative law to address significant evidence that detracts from the agency’s conclusion. The commenter stated that for the EPA to rely solely on the IRIS RfC, the EPA would need to explain why the CalEPA REL is incorrect and why the IRIS RfC reflects the best available science and risk assessment practices, particularly when the IRIS RfC and CalEPA REL thresholds are based on the same science and when the EPA relied upon CalEPA RELs at several other points in its proposal (e.g., the EPA used the CalEPA REL for acute inhalation exposure to HCl as the basis for its CAA section 112(d)(4) standards). If the EPA considers CalEPA’s acute REL for HCl to reflect a reliable value, then the commenter stated it is arbitrary to disregard CalEPA’s chronic REL for HCl. The commenter further noted the EPA relied upon the CalEPA chronic REL for HF in order to determine a threshold for HF and argued that using the CalEPA REL for HF but not for HCl is arbitrary.

*Response:* At an initial point, with respect to the comment that different agencies have identified different thresholds and so “as a matter of law” there is no “established” health threshold for HCl, the EPA disagrees that the phrase “has been established” in CAA section 112(d)(4) means that there is universal agreement on the

health threshold level and that differences between CalEPA and the EPA demonstrate that no health threshold “has been established.” The statute does not clearly identify who must establish the health threshold or how such threshold should be established. In the absence of such specificity in the statute, the EPA reads CAA section 112(d)(4) to authorize the EPA to set health-based limits where, in the EPA’s expert judgment, there is a health threshold for the pollutant below which no adverse health effects are expected to occur.

Further, we disagree with the comment that there is no established threshold at the RfC because CalEPA developed a reference value at a lower concentration than the RfC. The approaches used by both agencies are similar and assume a threshold below which adverse health effects would not be expected; however, there are some differences between agencies in methods for deriving the estimate for a threshold that may affect the final resulting values. Both agencies use the best available science to support their risk assessments. The EPA has an approach for selecting appropriate health benchmark values and, in general, this approach places greater weight on the EPA derived health benchmarks than those from other agencies. The approach favoring EPA benchmarks (when they exist) has been endorsed by the SAB and ensures use of values most consistent with well-established and scientifically-based EPA science policy.<sup>29</sup>

Specifically for HCl, we selected the IRIS RfC for HCl as the most appropriate chronic noncancer health threshold to use for this rule. In the case of HF, there is not an EPA RfC available and the only chronic reference value from an authoritative source and appropriate for use in this rule is the California REL.

*Comment:* Several commenters disagreed with the EPA’s decision to set a HBEL for HF. These commenters contended the EPA does not have the authority to set HF standards under CAA section 112(d)(4) because the scientific data supporting the EPA’s findings regarding the carcinogenic potential of HF are insufficient and unreliable. Three commenters asserted that the EPA should not adopt HBEL for

<sup>24</sup> IRIS Summary for Hydrogen Chloride. <http://www.epa.gov/iris/subst/0396.htm> (Accessed on July 24, 2015)

<sup>25</sup> California Office of Environmental Health Hazard Assessment (OEHHA), OEHHA Acute, 8-Hour and Chronic Reference Exposure Levels (REL)s. <http://www.oehha.ca.gov/air/Allrels.html> (last accessed Mar. 12, 2015).

<sup>26</sup> California OEHHA, Chronic RELs and Toxicity Summaries Using the Previous Version of the Hot Spots Risk Assessment Guidelines at 311 (1999), available at [http://oehha.ca.gov/air/hot\\_spots/2008/AppendixD3\\_final.pdf](http://oehha.ca.gov/air/hot_spots/2008/AppendixD3_final.pdf).

<sup>27</sup> EPA, Risk Assessment to Determine a Health-Based Emission Limitation for Acid Gases for the Brick and Structural Clay Products Manufacturing Source Category, May 19, 2014, Docket Item No. EPA-HQ-OAR-2013-0291-0132.

<sup>28</sup> S. Rep. No. 101-228, at 171.

<sup>29</sup> Science Advisory Board. Memorandum to Lisa Jackson, Administrator, U.S. EPA. Review of EPA’s draft entitled, “Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA’s Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing.” May 7, 2010. Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/\\$File/EPA-SAB-10-007-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf).

HF due to uncertainty about the vulnerabilities of children, infants, and fetuses to HF exposures at the REL concentration used by the EPA to set the HF emissions standards. Two commenters noted that the proposal states, "There is limited/equivocal evidence of the carcinogenic potential of HF" (79 FR 75641) and "[t]he EPA has not classified HF for carcinogenicity" (79 FR 75640) and questioned how the agency could be confident that HF is eligible to be a threshold pollutant if its status as a non-carcinogen is uncertain.

One commenter noted that the EPA failed to identify an established, well-defined health-based threshold, below which HF does not cause cancer, that is based on reliable science and has a high level of certainty. The EPA has stated that "carcinogenicity via inhalation of fluoride is not considered to be likely by most investigators reporting in the existing literature" (79 FR 75641) and that the EPA "has not classified HF for carcinogenicity" (79 FR 75640). The commenter stated that it is possible that HF causes cancer because increased rates of cancer have been observed in workers exposed to a mixture of chemicals that included fluoride<sup>30</sup> and noted that the EPA acknowledged data suggesting that those with occupational exposure to HF have greater than normal occurrences of cancer.<sup>31</sup> The commenter stated that, because of the data showing possible carcinogenic effect, as well as the data showing mutagenic effect in animals, the EPA does not have enough evidence to classify HF as a threshold pollutant with any level of confidence. The commenter stated that the EPA failed to explain how it weighed the conflicting evidence of HF's carcinogenicity and considered EPA's conclusion to be arbitrary and capricious. Three commenters noted that the EPA does not consider HF in its IRIS database but noted that HF breaks down into fluorine, which is included in IRIS.<sup>32</sup> One commenter stated that IRIS indicates no data are available to determine an RfC for chronic inhalation exposure to fluorine.<sup>33</sup> This commenter further noted that IARC "has determined that the carcinogenicity of fluoride to humans is not

classifiable."<sup>34</sup> Another commenter stated that health-based standards should be considered only for HAP that are contained in IRIS with a high level of confidence in the RfC.

One commenter noted that although the National Air Toxics Assessment (NATA) database does not contain HF,<sup>35</sup> the database does provide evidence that HF has a mutagenic effect in animals. This conclusion was supported by other scientific reviews<sup>36</sup> and by the National Academy of Sciences (NAS), which states that "the overall evidence from human animal studies is mixed" on the question of whether fluoride is carcinogenic when inhaled.<sup>37</sup>

Four commenters questioned the EPA's reliance on a CalEPA risk assessment, noting that the CalEPA REL is based on a study of adults exposed to HF in the workplace<sup>38</sup> and therefore, did not include any children. Two commenters stated that a 10X "intraspecies" factor was applied to account for variability among humans, but noted that CalEPA expressed concern about "the potentially greater susceptibility of children to the effects of inhaled fluorides, considering the rapid bone growth in early years."<sup>39</sup> One commenter recommended the EPA use an additional default factor of at least 10X to account for uncertainty regarding health risks to children, infants, and fetuses. The commenter stated that a 10X factor would be consistent with the NAS recommendation<sup>40</sup> and with the 10X factor enacted by Congress in the Food Quality Protection Act (FQPA).<sup>41</sup> Another commenter stated that recent

science not considered at the time CalEPA adopted the REL provides further support for prior research showing that HF has neurodevelopmental effects on children and that children living in high-fluoride areas have been observed to have lower IQ scores than those living in low-fluoride areas.<sup>42</sup> The commenter asserted that the adverse effects of fluoride on children are likely to be more severe, and long-lasting, compared with effects on adults.

One commenter stated that the CalEPA REL is based on a study that only examined the increased bone density (skeletal fluorosis) endpoint and noted that CalEPA stated that "[t]he primary uncertainty in the study was the lack of a comprehensive health effects examination."<sup>43</sup> The commenter stated that the EPA does not know whether neurodevelopmental harm, or other health effects, are more sensitive than skeletal harm; therefore, the EPA cannot lawfully set a "safe" threshold at a concentration that poses "no risk" of health effects with "an ample margin of safety" based on a study that lacks "a comprehensive health effects examination."

Another commenter asserted that the EPA has insufficient data showing exposure to HF at the REL value "presents no risk" of harm to other bodily systems. The commenter noted that HF is a possible reproductive toxin,<sup>44</sup> that occupational studies of women exposed to fluoride identified increased rates of menstrual irregularities,<sup>45</sup> and that animal studies have found that fluoride impairs reproduction and increases the rates of fetal bone and teeth malformation.<sup>46</sup> In addition, chronic inhalation of hydrofluoric acid can cause irritation and congestion of the nose and throat

<sup>34</sup> ATSDR, Toxicological Profile for Fluorides, Hydrogen Fluoride, and Fluorine at 8.

<sup>35</sup> EPA, National Scale Air Toxics Assessment Overview: The 33 Pollutants, <http://www.epa.gov/ttn/atw/nata/34poll.html> (last updated Jan. 6, 2015).

<sup>36</sup> See, e.g., National Research Council of the National Academies, Emergency and Continuous Exposure Guidance Levels for Selected Submarine Contaminants vol.3 at 91–92, available at <http://www.ncbi.nlm.nih.gov/books/n/nap12741/pdf>.

<sup>37</sup> National Research Council of the National Academies, Emergency and Continuous Exposure Guidance Levels for Selected Submarine Contaminants vol.3 at 91–92, available at <http://www.ncbi.nlm.nih.gov/books/n/nap12741/pdf>.

<sup>38</sup> Derryberry O.M., et al., Fluoride exposure and worker health-The health status of workers in a fertilizer manufacturing plant in relation to fluoride exposure, 6 Arch. Environ. Health. 503 (1963).

<sup>39</sup> OEHHA Chronic RELs and Toxicity Summaries, at 280.

<sup>40</sup> National Research Council of the National Academies, Science and Decisions: Advancing Risk Assessment, at 190–93 (2009).

<sup>41</sup> 21 U.S.C. 346a(b)(2)(C) (requiring that, in establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, "for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied" to protect infants and children).

<sup>42</sup> See Choi, A.L., et al., Developmental Fluoride Neurotoxicity: A Systematic Review and Meta-Analysis, 120 *Environ. Health Perspect.* 1362 (Oct. 2012), <http://ehp.niehs.nih.gov/1104912/> (reviewing and discussing findings from over 20 studies); Choi, A.L., et al., Association of Lifetime Exposure to Fluoride and Cognitive Functions in Chinese Children: A Pilot Study, 47 *Neurotox. & Teratology* 96 (Jan.–Feb. 2015).

<sup>43</sup> OEHHA, Chronic RELs and Toxicity Summaries, at 280.

<sup>44</sup> Massachusetts Toxics Use Reduction Institute, Massachusetts Chemical Fact Sheet: Hydrofluoric Acid, at 1, available at [http://www.turi.org/content/download/3663/44840/file/Fact\\_Sheet\\_Hydrofluoric\\_Acid.pdf](http://www.turi.org/content/download/3663/44840/file/Fact_Sheet_Hydrofluoric_Acid.pdf).

<sup>45</sup> EPA, Health Issue Assessment: Summary Review of Health Effects Associated with Hydrogen Fluoride and Related Compounds, EPA/600/8–89/002F (1988).

<sup>46</sup> ATSDR, Toxicological Profile for Fluorides, Hydrogen Fluoride and Fluorine; EPA, Health Issue Assessment: Summary Review of Health Effects Associated with Hydrogen Fluoride and Related Compounds.

<sup>30</sup> Gallerani, M., et al., Systemic and topical effects of intradermal hydrofluoric acid, 16 *Am. J. Emer. Med.* 521, 522 (1998).

<sup>31</sup> EPA, Technology Transfer Network Air Toxics Web site: Hydrogen Fluoride, <http://www.epa.gov/ttn/atw/hlthef/hydrogen.html> (last updated Oct. 18, 2013).

<sup>32</sup> EPA, Integrated Risk Information System: Fluorine (Soluble Fluoride) (CASRN 7782–41–4), <http://www.epa.gov/iris/subst/0053.htm> (last updated Oct. 31, 2014).

<sup>33</sup> Id.

and bronchitis,<sup>47</sup> and animal studies found increased rates of kidney and liver damage from hydrofluoric acid inhalation.<sup>48</sup> Further, HF readily penetrates the skin, causing deep tissue layer destruction,<sup>49</sup> and ingestion of HF may result in vomiting and abdominal pain, with painful necrotic lesions, hemorrhagic gastritis, and pancreatitis reported after significant exposure.<sup>50</sup>

The commenter stated the CalEPA REL was developed by CalEPA using an outdated version of CalEPA's Hot Spots Risk Assessment Guidelines (1999) that has been "superseded" by the more recent guidelines released in February 2015.<sup>51</sup> The commenter noted the 1999 version required updating in part because it did not include sufficient consideration of "infants and children in assessing risks from air toxics."

*Response:* The EPA has not reviewed HF in the IRIS program. However, we concur with the two recent authoritative assessments by ATSDR (2003)<sup>52</sup> and the European Union (2002)<sup>53</sup> that the

<sup>47</sup> CalEPA, Technical Support Document for the Determination of Noncancer Chronic Reference Exposure Levels.

<sup>48</sup> EPA, Health Issue Assessment: Summary Review of Health Effects Associated with Hydrogen Fluoride and Related Compounds.

<sup>49</sup> Burgher, Francois, *et al.*, Experimental 70% hydrofluoric acid burns: histological observations in an established human skin explants *ex vivo* model. 30.2 Cutaneous & Ocular Toxicology 100 (2011).

<sup>50</sup> CDC, National Institute for Occupational Safety and Health (NIOSH): Hydrogen Fluoride/Hydrofluoric Acid, [http://www.cdc.gov/niosh/ershdb/emergencypresponsecard\\_29750030.html](http://www.cdc.gov/niosh/ershdb/emergencypresponsecard_29750030.html).

<sup>51</sup> OEHHA Chronic RELs and Toxicity Summaries at 1; CalEPA, OEHHA, Air Toxics Hot Spots Program: Guidance Manual for Preparation of Health Risk Assessments (Feb. 2015), available at [http://oehha.ca.gov/air/hot\\_spots/2015/2015GuidanceManual.pdf](http://oehha.ca.gov/air/hot_spots/2015/2015GuidanceManual.pdf).

<sup>52</sup> Agency for Toxic Substances and Disease Registry (2003)—"Although elevated cancer rates have been reported in some occupational groups exposed to hydrogen fluoride and fluoride dusts, these studies were not controlled for the multiple substance exposures to which industrial workers are generally exposed. Because of these multiple exposures and the problem inherent in all occupational studies in identifying appropriate reference populations, only limited evidence from such studies is specifically relevant to the investigation of possible carcinogenic effects of long-term dermal exposure to hydrofluoric acid and inhalation exposure to hydrogen fluoride and/or fluoride dusts in human beings. As noted previously, IARC has determined that the carcinogenicity of fluoride to humans is not classifiable."

<sup>53</sup> European Union Risk Assessment Report (2001)—"Carcinogenicity studies, in which HF has been tested, are not available. Studies with NaF may provide insight in the carcinogenicity of HF, especially for systemic tumours. With the latter substance 4 animal studies have been performed, 2 in which NaF was supplied in the drinking water to rats and mice, and two in which NaF was administered via the diet, again to rats and mice . . . In the rat drinking water study, equivocal indications for osteosarcomas in males were obtained, but the rat diet study was negative,

available evidence does not support classifying HF as "Carcinogenic to Humans," "Likely to Be Carcinogenic to Humans" or as having "Suggestive Evidence of Carcinogenic Potential" (U.S. EPA Guidelines for Carcinogen Risk Assessment (2005)).

All of the studies cited by the commenter are from exposure to fluoride and not from inhalation exposures to HF. Neurodevelopmental effects may be relevant to high fluoride exposures, but the existing evidence shows these effects may occur at fluoride exposure levels beyond those that would cause respiratory effects if HF were the sole source of exposure. In the study of Lund (1997),<sup>54</sup> plasma fluoride concentrations were shown to increase in the nanogram per milliliter (ng/ml) range from exposures to HF in the mg/m<sup>3</sup> level (*e.g.*, elevations of approximately 20 nanograms fluoride per milliliter in plasma resulted from 1-hour exposure to 2 mg/m<sup>3</sup> HF, with notable respiratory and eye irritation effects). Reproductive and developmental effects in rats have been noted from experiments<sup>55</sup> with plasma F levels in the 150 ng/ml range maintained for over 4 months. The primary issue in causing neurodevelopmental effects (which have yet to be quantified) is likely associated with aggregate and cumulative exposure from multiple sources of fluorides (*e.g.*, water, food, toothpaste) which are

despite clear indications of fluoride intoxication. The mouse drinking water study was also negative. The mouse diet study was confounded by the presence of a retrovirus which may have (co)-induced the growth of benign osteomas thus thwarting the interpretation of the study. In the diet studies (Maurer *et al.* 1990; Maurer *et al.* 1993) bone fluoride levels were higher than in the drinking water studies (NTP 1990), while in the diet studies no indications for osteosarcomas were obtained. Furthermore, the osteomas were considered to be reminiscent of hyperplasias rather than true bone neoplasms. It was concluded that the available data is sufficient to suggest that fluoride is not a carcinogenic substance in animals (Janssen and Knaap 1994) . . . Based on epidemiological data IARC (1982) concluded that the evidence for carcinogenicity of orally taken fluoride in humans is inadequate. Recent studies (cited in CEPA 1993; Janssen and Knaap 1994) did not supply evidence of a relationship between fluoride in drinking water and cancer mortality, either. US-EPA, reviewing the epidemiological data for fluoride, stated that no conclusion can be drawn as to the carcinogenicity of fluoride after inhalatory exposure, because in all studies available, humans were exposed to other substances as well (Thiessen 1988)."

<sup>54</sup> Lund K, Ekstrand J, Boe J, Sørstrand P, and Kongerud J. (1997) Exposure to hydrogen fluoride: an experimental study in humans of concentrations of fluoride in plasma, symptoms, and lung function. *Occup Environ Med.* 54(1):32-37.

<sup>55</sup> Oencue, M, Kocak, A, Karaoz, E; Darici, H; Savilk, E; and Gultekin, F (2007) Effect of long-term fluoride exposure on lipid peroxidation and histology of testes in first- and second-generation rats. *Biological Trace Element Research* 118:260-268.

greater contributors to total fluoride body burden and uncontrollable variables in establishing this rule, which deals with exposures to HF only.

The EPA also disagrees with the comment that a children's default safety factor of 10 should be added to the CalEPA REL for HF. In response to the 10X factor enacted by Congress in the FQPA (1996)<sup>56</sup> to the EPA non-cancer reference value derivation, the agency evaluated its methods for considering children's risk in the development of reference values. As part of its response, the EPA (*i.e.*, the Science Policy Council and Risk Assessment Forum) established the RfD/RfC Technical Panel to develop a strategy for implementing the FQPA and examine the issues relative to protecting children's health and application of the 10X safety factor. One of the outcomes of the Technical Panel's efforts was an in depth review of a number of issues related to the RfD/RfC process (U.S. EPA 2002). The most critical aspect in the derivation of a reference value pertaining to the FQPA has to do with variation between individual humans and is accounted for by a default uncertainty factor when no chemical-specific data are available. The EPA reviewed the default UF for inter-human variability and found the EPA's default value of 10 adequate for all susceptible populations and lifestages, including children and infants. The EPA also recommends the use of chemical-specific data in preference to default uncertainty factors when available (U.S. EPA, 1994, 2011) and is developing Agency guidance to facilitate consistency in the development and use of data-derived extrapolation factors for RfCs and reference doses (RfDs) (U.S. EPA, 2011).<sup>57 58</sup> In agreement with the recommendations of the RfC review, CalEPA chronic REL for HF was derived using an inter-individual uncertainty factor of 10, which is considered adequate by the EPA for accounting for all susceptible populations and lifestages, including children and infants.

Regarding the comment that CalEPA's Hot Spots Risk Assessment Guidelines

<sup>56</sup> U.S. Environmental Protection Agency, Pesticide: Regulating Pesticides. The Food Quality Protection Act (FQPA). 1996. Available at <http://www.epa.gov/pesticides/regulating/laws/fqpa/backgrnd.htm>.

<sup>57</sup> U.S. EPA (1994). *Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry*. (EPA/600/8-90/066F). Research Triangle Park, NC. Docket Item No. EPA-HQ-OAR-2013-0291-0160.

<sup>58</sup> U.S. EPA (2011). Office of the Science Advisor, Risk Assessment Forum. *Recommended Use of Body Weight<sup>1/4</sup> as the Default Method in Derivation of the Oral Reference Dose*. February 2011. EPA/100/R11/0001.

(1999) have been “superseded” by the more recent guidelines released in February 2015, the EPA reviewed the February 2015 Guidelines information provided by the commenter and concluded that this information does not include methods for conducting hazard identification and dose response assessments, which are the analyses that preclude the derivation of a reference value. Therefore, the information provided by the commenter does not apply to the CalEPA REL derivation methods.

The commenter’s assertion that the NATA database does not contain HF is incorrect; NATA 2005 (cited above by the commenter) does include noncancer risk estimates for HF. The HF cancer risks are not included in NATA because a quantitative cancer analysis for HF does not exist.

*Comment:* Several commenters disagreed with the EPA’s decision to set a HBEL for Cl<sub>2</sub> and stated the EPA does not have the authority to set Cl<sub>2</sub> standards under CAA section 112(d)(4) because the EPA does not have reliable scientific data demonstrating a “safe” threshold for Cl<sub>2</sub> and has not demonstrated Cl<sub>2</sub> presents no cancer risk. Two commenters noted that in the proposal, the EPA stated that, “the agency presumptively considers Cl<sub>2</sub> to be a threshold pollutant.” The commenters asserted that a presumption is not adequate for EPA to justify setting a health-based standard for Cl<sub>2</sub> under CAA section 112(d)(4).

One commenter stated that it is possible that Cl<sub>2</sub> is carcinogenic and noted that Cl<sub>2</sub> has not undergone a complete evaluation and determination of human carcinogenic potential under the IRIS program.<sup>59</sup> The IARC and the Department of Health and Human Services (DHHS) have not classified Cl<sub>2</sub> gas for human carcinogenicity. The commenter stated that the absence of data showing carcinogenicity is not the same as data demonstrating that a substance is not carcinogenic.

According to the commenter, Congress authorized CAA section 112(d)(4) standards only where a threshold “has been established.” In other words, there must be an already-established threshold for which there is direct evidence that the pollutant presents “no” harm at the threshold level of exposure, and the law requires “well-established” factual evidence.<sup>60</sup> The commenter asserted that the EPA is not authorized to set risk-based

standards based on a “presumption” of the existence of a safe level of exposure and that by doing so, the EPA would violate the law and fail to ensure adequate protection from the health risks of hazardous pollution.

The commenter stated that the EPA cannot set a health threshold for Cl<sub>2</sub> based on a chronic inhalation study on monkeys because that study did not determine a NOAEL. The commenter asserted that CAA section 112(d)(4) does not permit risk-based standards where a NOAEL has not been determined. The commenter stated that, at a minimum, Congress required that a threshold be based on the “‘no observable [adverse] effects level’ (NOAEL) below which human exposure is presumably ‘safe.’”<sup>61</sup> If there is no established non-zero “threshold” level at which it has been shown that the pollutant has no deleterious health effects, then the commenter asserted that the EPA cannot be certain that exposure to the pollutant at a given level presents “no” harm.

Two commenters stated that IRIS contains “no data” on an RfC for chronic inhalation exposure.<sup>62</sup> The ATSDR MRL on which the proposed Cl<sub>2</sub> threshold is based is a “screening value[] only” and “[is] not [an] indicator[] of health effects.”<sup>63</sup> According to the ATSDR, “Exposures to substances at doses above MRLs will not necessarily cause adverse health effects and should be further evaluated,”

“MRLs are intended to serve only as a screening tool to help you decide if you should more closely evaluate exposures to a substance found at a site,” and “uncertainties are associated with [the] techniques” used to derive MRLs.<sup>64</sup>

One commenter stated that the MRL does not account for the potentially greater susceptibility of children, infants, and fetuses to Cl<sub>2</sub> exposures<sup>65</sup> and noted that CalEPA has recognized that Cl<sub>2</sub> is a toxic air contaminant “that may disproportionately impact infants and children” because it can exacerbate asthma.<sup>66</sup> Therefore, the commenter

asserted the MRL does not reflect an “established” safe health threshold at which exposure presents “no” adverse effects and that it is unlawful for the EPA to set CAA section 112(d)(4) standards for Cl<sub>2</sub>.

*Response:* The EPA disagrees with the comment. As part of the risk analysis conducted to support this rule, the EPA thoroughly evaluated all the available and relevant scientific evidence on Cl<sub>2</sub> (as discussed in detail previously in this section) and concluded that there is no evidence that Cl<sub>2</sub> is a carcinogen and that this information is sufficient to support this regulatory decision. The MRL for Cl<sub>2</sub> was developed using the benchmark dose analysis method, which has been widely adopted across the risk assessment community and by the EPA’s Risk Assessment Forum<sup>67</sup> as a more reliable estimate of a threshold for an effect than a NOAEL or LOAEL. As a result, the REL for Cl<sub>2</sub> does define a threshold.

Regarding the assertion that the MRL does not take into consideration the potential for greater potential effects in children, in the development of the Toxicological Profile for Chlorine,<sup>68</sup> ATSDR performed an exhaustive review of all of the relevant health effects data available at the time. Until new information becomes available, the Cl<sub>2</sub> MRL is the most credible, scientifically grounded toxicity assessment for Cl<sub>2</sub> and the most appropriate reference value to use in this regulatory action.

In the light of the absence of evidence of carcinogenic risk from Cl<sub>2</sub> exposure and the evidence of an existing threshold below which Cl<sub>2</sub> is not expected to cause adverse effects, the EPA considers it appropriate to set health threshold standards under CAA section 112(d)(4) for Cl<sub>2</sub>.

*Comment:* One commenter referenced an NAS review of chemical health evaluations in the United States that concluded improvements in both chemical testing and risk assessment are needed to assure current risk evaluations protect people from toxic chemicals.<sup>69</sup> The NAS recommended the EPA use “A consistent, unified

<sup>59</sup> S. Rep. No. 101–228, at 171, 176.

<sup>60</sup> EPA, Integrated Risk Information System: Chlorine.

<sup>61</sup> ATSDR, Public Health Assessment Guidance Manual (2005 Update): Appendix F, <http://www.atsdr.cdc.gov/hac/PHAManual/appf.html> (last updated Nov. 30, 2005).

<sup>62</sup> ATSDR, Toxicological Profile for Chlorine, at 14.

<sup>63</sup> ATSDR, Toxicological Profile for Chlorine at 20–21 (observing that a value similar to the MRL could be calculated using the lowest observed adverse effect level (LOAEL) approach if an uncertainty factor of only 3 for human variability is used and no child-safety uncertainty factor is used).

<sup>64</sup> CalEPA, Prioritization of Toxic Air Contaminants Under the Children’s Environmental Health Protection Act, at 27–28.

<sup>65</sup> U.S. EPA (2012) Benchmark Dose Technical Guidance. Risk Assessment Forum, Washington, DC 20460. EPA/100/R–12/001, June 2012. Available online at [http://www2.epa.gov/sites/production/files/2015-01/documents/benchmark\\_dose\\_guidance.pdf](http://www2.epa.gov/sites/production/files/2015-01/documents/benchmark_dose_guidance.pdf).

<sup>66</sup> Agency for Toxic Substances and Disease Registry (ATSDR). 2010. Toxicological profile for Chlorine. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

<sup>67</sup> See National Research Council of the National Academies, Toxicity Testing in the Twenty-First Century: A Vision and a Strategy (2007); National Research Council of the National Academies, Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008); NAS, Science and Decisions.

<sup>59</sup> EPA, Integrated Risk Information System: Chlorine, <http://www.epa.gov/iris/subst/0405.htm> (last updated Oct. 31, 2014).

<sup>60</sup> S. Rep. No. 101–228, at 171.



approach for dose-response modeling that includes formal, systematic assessment of background disease processes and exposures, possible vulnerable populations, and modes of action that may affect a chemical's dose-response relationship in humans; that approach redefines the RfD or RfC as a risk-specific dose that provides information on the percentage of the population that can be expected to be above or below a defined acceptable risk with a specific degree of confidence." The NAS also observed that "[n]oncancer effects do not necessarily have a threshold, or low-dose nonlinearity" and found that "[b]ecause the RfD and RfC do not quantify risk for different magnitudes of exposure but rather provide a bright line between possible harm and safety, their use in risk-risk and risk-benefit comparisons and in risk-management decision-making is limited."<sup>70</sup>

The commenter stated that there may be no safe threshold in the human population for many chemicals and that newer studies show many chemicals increase the risk of various noncancer health effects—such as reproductive harm and neurological effects—at low doses, without any scientifically identifiable threshold.<sup>71</sup> The commenter noted that even if a threshold is established for an individual, when risk is assessed across a diverse population, it is unlikely the same threshold applies to all individuals because some people are more vulnerable than others.

The commenter stated that, to address the fact that very low levels of non-carcinogen exposures can pose health risks, NAS recommended that cancer and chronic non-cancer risk assessment use the same approach.<sup>72</sup> The commenter noted that the use of RfCs for dose-response risk assessment of chronic non-cancer health effects may significantly underestimate risk: "For these health effects, risk assessments focus on defining the reference dose (RfD) or reference concentration (RfC), which is defined as a dose 'likely to be without an appreciable risk of deleterious effects' over a lifetime of exposure. In actual fact, these levels may pose appreciable risks."<sup>73</sup>

<sup>70</sup> Janssen, S., *et al.*, Strengthening Toxic Chemical Risk Assessments to Protect Human Health (2012), available at <http://www.nrdc.org/health/files/strengthening-toxic-chemical-riskassessments-report.pdf> (citing NAS, Science and Decisions).

<sup>71</sup> Janssen *et al.*, Strengthening Toxic Chemical Risk Assessments to Protect Human Health.

<sup>72</sup> NAS, Science and Decisions, at 8–9, 265–66.

<sup>73</sup> Janssen, S., *et al.*, Strengthening Toxic Chemical Risk Assessments to Protect Human Health at 10.

The commenter asserted that the EPA ignored the best available, current science showing that pollutants have health effects at low doses in its evaluation of health thresholds for HCl, HF, and Cl<sub>2</sub> and ignored NAS's recommendation that the EPA use similar approaches for chronic non-cancer as for cancer risk assessment, which presumes deleterious health effects for any amount of exposure. According to the commenter, the EPA lacked sufficient data to demonstrate that these pollutants do not cause harm at low levels of exposure over time and cannot be certain that there exists an established, safe health threshold at the proposed thresholds. The commenter also stated that, because it must be assumed that these pollutants cause harm at low doses, it is impossible for the EPA to meet the CAA's requirement for an "ample margin of safety." The commenter concluded the EPA's use of CAA section 112(d)(4) standards for HCl, HF, and Cl<sub>2</sub> is indefensible because the EPA determined the thresholds based on studies that did not identify a level at which no health effects were observed (*i.e.*, a NOAEL) and the EPA itself has low confidence in the proposed thresholds.

*Response:* The NAS has recognized that many of the recommended changes for the IRIS Program will need to be incorporated over a number of years and further recommended that assessments continue to be developed as the recommendations are implemented (*i.e.*, the regulatory process should not be halted until all recommendations can be enacted). Improvements will thus be made over time and the best science available will be used in the interim. Further, the EPA has a legal obligation to proceed with regulatory action based on the best, currently available tools.

The EPA's conclusion that HCl, HF and Cl<sub>2</sub> are threshold pollutants is based on the best available toxicity database considered in hazard identification and dose response assessments. There is agreement on using a similar threshold approach for these chemicals across agencies, *e.g.*, the EPA's IRIS Program, ATSDR and CalEPA. The toxicity assessments (which may include noncancer and/or cancer toxicity assessments) provided by these authoritative bodies are widely vetted through the scientific community and undergo rigorous peer review processes before they are published. In addition, the SAB has endorsed the use of the reference values derived by these sources to support EPA's risk assessments in the RTR program.

Specifically, none of the compounds discussed here has been classified as

carcinogenic or suggestive of the potential to be carcinogenic, individually or in combination by existing authoritative bodies including the EPA, CalEPA, IARC, OECD, and the European Community. In light of the absence of evidence of carcinogenic risk for any of these pollutants, and the evidence of an existing threshold below which HCl, HF and Cl<sub>2</sub> are not expected to cause adverse effects, the EPA considers it appropriate to set health threshold standards under CAA 112(d)(4) for these pollutants.

## 2. Co-Benefits

*Comment:* One commenter stated that the EPA's proposal not to set MACT standards for acid gases did not fully consider the co-benefits of controlling criteria pollutants. The commenter noted that the legislative history makes clear that employing a CAA section 112(d)(4) standard rather than a conventional MACT standard "shall not result in adverse environmental effect which would otherwise be reduced or eliminated."<sup>74</sup> The EPA asserted that where there is an established health threshold, the agency may weigh additional factors in making a judgment as to whether to set CAA section 112(d)(4) standards or MACT standards, including "[c]o-benefits that would be achieved via the MACT standard, such as reductions in emissions of other HAP and/or criteria pollutants" (79 FR 75622). The commenter asserted that it is impossible to make this assessment without evaluating the full collateral benefits of a MACT standard.

The commenter noted that the EPA has recognized that MACT standards for HCl in other source categories resulted in reductions in emissions of PM, hydrogen cyanide, and other criteria and HAP pollutants and has relied upon the co-benefits of these reductions as a basis for not setting risk-based standards for those other source categories.<sup>75</sup>

<sup>74</sup> S. Rep. No. 101–228, at 171.

<sup>75</sup> See, *e.g.*, National Emission Standards for Hazardous Air Pollutants from the Portland Cement Manufacturing Industry and Standards of Performance for Portland Cement Plants, 75 FR 54970, 54984 (Sept. 9, 2010) ("Setting technology-based MACT standards for HCl . . . would likely also result in additional reductions in emissions of mercury, along with condensable PM, ammonia, and semi-volatile compounds."); *id.* at 54,985 ("Setting an HCl standard under 112(d)(2) and (3) allows the Agency to also address" HCN, ammonia, and other pollutants.); National Emission Standards for Hazardous Air Pollutants from the Portland Cement Manufacturing Industry, 74 FR 21136, 21160 (May 6, 2009) ("[S]etting a MACT standard for HCl is anticipated to result in a significant amount of control for other pollutants emitted by cement kilns, most notably SO<sub>2</sub> and other acid gases, along with condensable PM, ammonia, and semi-volatile compounds."); 75 FR 32030

However, for BSCP and clay ceramics plants, the EPA only considered the co-benefits of reductions in sulfur dioxide (SO<sub>2</sub>). The commenter argued the EPA should have considered the significant reductions in PM, hydrogen cyanide, and other pollutants that would likely result from MACT standards for HCl, HF, and Cl<sub>2</sub>, as these are the same reductions that the EPA considered in its past rulemakings. The commenter stated that these reductions will provide enormous health and environmental benefits that would not occur if CAA section 112(d)(4) standards are finalized instead.

*Response:* Although not explicitly stated in the preamble to the proposed rule, the EPA agrees with the commenter that MACT standards for acid gases for BSCP manufacturing facilities are associated with additional reductions of PM emissions (approximately 460 tpy in the third year following promulgation of the standards) and non-Hg HAP metals emissions. No additional PM or non-Hg HAP metals emission reductions would be expected from sanitaryware tunnel kilns because it is anticipated that all sanitaryware tunnel kilns could meet the MACT floor emission limits for HF and HCl without additional APCD. The EPA has no information suggesting that HCN is emitted from BSCP or clay ceramics manufacturing facilities, so no reduction in HCN would be expected from MACT standards for HF, HCl, and Cl<sub>2</sub>.

For the past rulemakings in which the EPA considered co-benefits as part of a CAA section 114(d)(4) evaluation, the EPA did not quantify the PM emissions reductions associated with MACT standards (see 79 FR 75641, footnote 27), so a direct comparison of the co-benefits of the BSCP Manufacturing NESHAP and the Clay Ceramics Manufacturing NESHAP with the co-benefits of these other rules for PM is not possible. The only pollutant with quantified emissions reductions in the co-benefits analyses for these other rulemakings was SO<sub>2</sub>, so that was the pollutant highlighted in the co-benefits analysis for BSCP and clay ceramics at

("[S]etting conventional MACT standards for HCl as well as PM . . . would result in significant reductions in emissions of other pollutants, most notably SO<sub>2</sub>, non-condensable PM, and other non-HAP acid gases (e.g., hydrogen bromide) and would likely also result in additional reductions in emissions of mercury and other HAP metals (e.g., selenium)."); 76 FR 25051 ("[S]etting conventional MACT standards for HCl as well as PM . . . would result in significant reductions in emissions of other pollutants, most notably SO<sub>2</sub>, PM, and other non-HAP acid gases (e.g., hydrogen bromide) and would likely also result in additional reductions in emissions of Hg and other HAP metals (e.g., Se).").

proposal. The additional nationwide reductions of SO<sub>2</sub> that would be attributable to MACT standards for acid gases in the BSCP Manufacturing NESHAP are estimated to be only 4,700 tpy in the third year following promulgation of the standards. No additional nationwide reductions of SO<sub>2</sub> would be attributable to MACT standards for acid gases in the Clay Ceramics Manufacturing NESHAP because it is anticipated that all sanitaryware tunnel kilns could meet the MACT floor emission limits without additional APCD. As noted at proposal, these reductions are substantially lower than the co-benefits from MACT standards for other industries for which the EPA has decided not to set a HBEL, and it would not be expected to provide a significant public health benefit.

3. Ecosystem Impacts

*Comment:* One commenter expressed concern about the ecological impacts of the proposed HBEL for acid gases. The commenter stated that federal, state and local agencies have struggled for years to reduce emissions of SO<sub>2</sub> and other acid gases to prevent the devastating effects of acid rain on large ecosystems and noted the proposed standards would likely result in the acidification of the ecosystems in close proximity to BSCP and clay ceramics manufacturing sources. The commenter asserted the ecological impact analysis of the emissions standards for this proposal is inadequate.

*Response:* The EPA disagrees with the commenter that the ecological analysis is inadequate. The environmental screening analysis evaluated potential damage and reduced productivity of plants due to chronic direct exposure to HCl and HF emitted by clay ceramics manufacturing facilities and BSCP manufacturing facilities into the air. The chronic 90-day benchmarks used in the environmental risk screen for the acid gases are shown in Table 7 of this preamble and discussed in the following section.

TABLE 7—ACID GAS BENCHMARKS INCLUDED IN THE ENVIRONMENTAL RISK SCREEN

Acid gas	Chronic 90-day benchmark in µg/m <sup>3</sup> <sup>a</sup>
Hydrochloric acid—LOEL	b <sup>50</sup>
Hydrofluoric acid—Plant Community LOEL	0.5
Hydrofluoric acid—Plant Community LOEL	0.4

<sup>a</sup> Micrograms per cubic meter.

<sup>b</sup> Note that the human health RfC is 20 µg/m<sup>3</sup>, which is lower than the ecological benchmark.

For HCl, the EPA identified chronic benchmark concentrations as described in a 2009 EPA document on RTR risk assessment methodologies.<sup>76</sup> The chronic benchmark for HCl was based on a lowest observed effects level (LOEL) from a short-term exposure (20 minutes) that related HCl concentration to “changes” in the leaves of 7 out of 8 plant species as reported by Lerman *et al.*<sup>77</sup> It was the lowest exposure concentration at which effects of any type were seen (visible injury to some proportion of leaves). Haber’s law was used to extrapolate the 1.5 mg/m<sup>3</sup> LOEL concentration (20-minute exposure) to a 0.5 mg/m<sup>3</sup> concentration expected to produce the same effect after 1 hour. The 1-hour estimated LOEL was extrapolated to a chronic benchmark by dividing by a factor of ten to yield 0.050 mg/m<sup>3</sup>, or 50 µg/m<sup>3</sup>.

For HF, the EPA used two chronic benchmark concentrations for plants in the environmental screening analysis. The value of 0.5 µg HF/m<sup>3</sup> is based on the Washington State criterion for gaseous HF and represents a LOEL. The value of 0.4 µg HF/m<sup>3</sup> is based on the Environment Canada criteria and also represents a LOEL.

To protect vegetation from adverse effects resulting from HF exposure, the Canadian Council of Ministers of the Environment<sup>78</sup> recommends that HF concentrations not exceed 0.4 µg/m<sup>3</sup> over a 30- to 90-day period; HF concentrations can be higher for shorter exposures). Environment Canada<sup>79</sup> defined the effect represented by the level of 0.4 µg HF/m<sup>3</sup> as:

The level above which there are demonstrated effects on human health and/

<sup>76</sup> U.S. EPA, 2009. Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA’s Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing. EPA-452/R-09-006. Docket Item No. EPA-HQ-OAR-2013-0291-0044.

<sup>77</sup> Lerman, S., O.C. Taylor, and E.F. Darley, 1976. Phytotoxicity of Hydrogen Chloride Gas with a Short-Term Exposure. Atmospheric Environment, Vol. 10, pp. 873-878.

<sup>78</sup> CCME. 1999b. Canadian National Ambient Air Quality Objectives: Process and Status. In: Canadian Environmental Quality Guidelines, 1999, Canadian Council of Ministers of the Environment, Winnipeg. Publication No. 1299, ISBN 1-896997-34-1. Available at <http://ceag-rcqe.ccme.ca/download/en/133/>.

<sup>79</sup> EC. (Environment Canada). 1996. National Ambient Air Quality Objectives for Hydrogen Fluoride (HF). Science Assessment Document. A Report by the CEPA/FPAC Working Group on Air Quality Objectives and Guidelines. July. ISBN 0-662-25641-7, Catalogue En42-17/6-1997. Available online at: [http://www.bape.gouv.qc.ca/sections/mandats/ap50\\_rio\\_tinto\\_alcan/documents/DQ3.1.1.pdf](http://www.bape.gouv.qc.ca/sections/mandats/ap50_rio_tinto_alcan/documents/DQ3.1.1.pdf).

or the environment. It is scientifically based and defines the boundary between the lowest observed adverse effect level (LOAEL) and the no observed adverse effect level (NOAEL). It is considered to be the level of exposure just below that most likely to result in a defined and identifiable but minimal effect. The reference levels have no safety factors applied to them, as they are related directly to the LOAEL, and are the most conservative estimates of the effect level.

High concentrations of HF in the air have also been linked to fluorosis in livestock. However, the HF concentrations at which fluorosis in livestock occur are higher than those at which plant damage begins. Therefore, the benchmarks for plants are protective of both plants and livestock.

For Clay Ceramics Manufacturing facilities, the environmental risk screen indicated that the area-weighted average modeled concentration of HCl around each facility (*i.e.*, the area-weighted average concentration of all offsite data points in the modeling domain) did not exceed the ecological benchmark. In addition, the ecological benchmark was not exceeded at any offsite receptor location for any facility. For HF, the environmental risk screen indicated that the area-weighted average modeled concentration of HF around each Clay Ceramics Manufacturing facility did not exceed the ecological benchmark. There were multiple facilities with modeled concentrations of HF at offsite receptor locations that exceeded the ecological benchmark, but the area over which the value was exceeded was no greater than 1 percent of the offsite modeling domain for each facility, indicating that there would not be any significant or widespread environmental effects.

For BSCP Manufacturing facilities, the environmental risk screen indicated that the area-weighted average modeled concentrations of HCl and HF around each facility (*i.e.*, the area-weighted average concentration of all offsite data points in the modeling domain) did not exceed the ecological benchmarks. In addition, the area over which the HCl or HF benchmarks were exceeded was less than 1 percent of the offsite modeling domain for each facility in the category, indicating that there would not be any significant or widespread environmental effects.

The EPA did not conduct an assessment of the potential for emissions of HCl to cause acidification in close proximity to the sources in this category. Acid deposition, more commonly known as acid rain, primarily occurs when emissions of SO<sub>2</sub> and nitrogen oxides (NO<sub>x</sub>) react in the atmosphere (with water, oxygen, and oxidants) to form various acidic

compounds.<sup>80</sup> Although some studies indicate that HCl emissions could contribute to acidification around emission sources in certain environments,<sup>81</sup> its overall effect relative to NO<sub>x</sub> and SO<sub>2</sub> emissions would be small. In addition, the commenter did not provide any data to support their assertion that the proposed standards would result in the acidification of the ecosystems in close proximity to BSCP and structural clay products manufacturing facilities.

#### 4. Cumulative Effects

*Comment:* One commenter expressed concern that the EPA did not fully consider the cumulative effects of exposure to HAP when proposing the health-based standard under CAA section 112(d)(4). The commenter asserted that the agency assumed there are no cumulative health and environmental impacts of concern and argued the EPA cannot ensure that its proposed standards include an ample margin of safety without properly accounting for the additive and/or synergistic effects of multiple pollutants and the cumulative effects of nearby emissions.

Another commenter stated that the EPA made no adjustments to the HBEL it selected to account for the potential for harm from exposures other than to the amounts of HCl, HF, and Cl<sub>2</sub> it proposed to allow. Specifically, the EPA must consider emissions of HCl, HF, and Cl<sub>2</sub> and other pollutants with biologically similar endpoints (*i.e.*, that cause respiratory harm) from sources in the source category as well as from any co-located sources and other stationary or mobile sources located such that their emissions affect people who are also exposed to the emissions subject to the NESHAP. The commenter asserted that the EPA cannot lawfully set limits “with an ample margin of safety” when it ignores other sources of exposure and cumulative health effects. The commenter asserted that, to protect exposed populations, the regulated sources must reduce their emissions to a level that ensures the total concentration of pollutants will remain below the pollutants’ respective health thresholds. The commenter asserted that the EPA’s decision to ignore the impact of other emissions and background concentrations in the implementation of the HBEL is therefore arbitrary,

capricious, an abuse of discretion, and otherwise not in accordance with law.

If the ambient concentration of a particular pollutant is already at or near the health threshold, the commenter asserted that an additional source of that pollutant or another pollutant with a biologically similar endpoint can push the exposure over the threshold, even if the additional source emits the pollutant at low concentrations. The total risk that is unacceptable for the most-exposed person in each source category must be reduced to consider the cumulative effect of these additional exposures and to create a total risk from all regulated source categories. The commenter stated that EPA’s assessment of cumulative risks posed by HCl, HF, and Cl<sub>2</sub> emissions ignored emissions from co-located sources (for BSCP kilns), nearby sources and all other potential sources that could contribute to background levels. The commenter noted that the EPA has emissions information about co-located and nearby sources in its own databases but failed to evaluate whether cumulative exposures would exceed the health thresholds and to consider combined exposures. The commenter reviewed reports from the EPA’s Enforcement and Compliance History Online (ECHO) Web site for a number of BSCP and clay ceramics facilities and provided notes on other major source facilities in close proximity. The commenter stated that the EPA’s justifications regarding cumulative nearby emissions are legally inadequate and factually inaccurate. The commenter stated that general assertions that other operations are not “commonly” co-located with BSCP and clay ceramics facilities, that such facilities are “typically” located on large tracts of land, and that facilities are set back from property lines in rural areas are insufficient to set the emissions standard at a level that protects all people living near such facilities.

The commenter stated that information in the EPA’s own databases demonstrates that BSCP and clay ceramics facilities are not predominantly located in rural, sparsely populated areas, as the EPA assumes. Many of the BSCP facilities are located in urban areas, including Boral Bricks in Terre Haute, Indiana; Hanson Brick in Columbia, South Carolina; General Shale Brick in Denver, Colorado; and Cherokee Brick & Tile in Macon, Georgia.<sup>82</sup> Similarly, in the clay

<sup>80</sup> National Acid Precipitation Assessment Program Report to Congress, 2005. Also see—<http://www.epa.gov/acidrain/reducing/index.html>.

<sup>81</sup> Hydrochloric Acid: An Overlooked Driver of Environmental Change. Environmental Science and Technology 2011, 45, 1187–1894.

<sup>82</sup> U.S. Census Bureau, 2010 Census Urban and Rural Classification and Urban Area Criteria: Lists of 2010 Census Urban Areas, [http://www2.census.gov/geo/docs/reference/ua/ua\\_list\\_all.xls](http://www2.census.gov/geo/docs/reference/ua/ua_list_all.xls).

ceramics source category, only two of the sources are located in areas considered “rural” by the United States Census Bureau: American Marazzi Tile in Sunnyvale, Texas, and the Kohler Wisconsin Plant outside of Sheboygan, Wisconsin.<sup>83</sup>

The commenter stated that the EPA’s assessment of cumulative risks does not meet generally accepted good practices in risk assessment. The SAB recommended in May 2010 that the EPA incorporate “aggregate and cumulative risks, including background concentrations and contributions from other sources in the area” into its risk analysis.<sup>84</sup> The commenter stated that the EPA must assess the total and cumulative risk burden, rather than only looking at each type of risk in a discrete, separate way, and the EPA should be integrating its assessments and performing a “comprehensive risk assessment” as the NAS has emphasized. After first assessing the total cancer, chronic non-cancer, and acute risks, for both inhalation and multipathway exposure, the EPA also must assess the total risks.<sup>85</sup> The EPA must aggregate health risk for each pollutant, and each type of health risk, to create a cumulative risk determination for an individual with maximum exposure. Without a combined health risk metric, the EPA cannot make an ample margin of safety determination that is based on the full picture of health risk for these source categories.

Finally, the commenter stated that this proposal is contrary to the EPA’s recent conclusion in its regulation of power plant electric generating units that “the potential cumulative public health and environmental effects of acid gas emissions” did not allow for CAA section 112(d)(4) standards.<sup>86</sup> In that rulemaking, the EPA did not receive facility-specific emissions information for all the acid gases from units in the

source category, co-located sources, and all nearby sources. The EPA concluded that “cumulative impacts of acid gases on public health were not assuaged by the comments received.” The commenter stated that the EPA did not consider that information in this rulemaking either, and just as in the power plant rulemaking, HBEL are not lawful.

*Response:* The EPA disagrees with the commenter that the EPA did not consider the potential impacts of nearby BSCP and clay ceramics facilities or other nearby facilities in the determination of the HBEL for each source category. The limit reflects the impacts of all facilities in the source category. While the risk assessment did not perform a detailed modeling analysis of other nearby facilities, based on a proximity analysis of sources emitting acid gases, the EPA concludes that the emissions from these facilities would not have significantly impacted the analysis for several reasons. First, the limit reflects a hazard index (HI) less than or equal to one at the highest impacted receptor at each facility. For source categories like BSCP and clay ceramics where emission release heights are low, the highest impacted receptor is always very near (e.g., shares a common fence line) the facility, and ambient concentrations fall quickly with distance from the source. Because of this, other facilities would have to be very near a BSCP or clay ceramics facility and have relatively high emissions to have any significant impact on the receptor with the highest estimated concentration from the BSCP or clay ceramics emissions. As in risk assessments performed under the Risk and Technology Review program, the EPA did not model the nearby sources in the National Emissions Inventory (NEI) because that inventory has not received the same level of review and quality assurance that the BSCP emissions have for the purposes of this rulemaking.

Although the EPA did not model the other nearby facilities, the EPA did compare the location of all sources emitting acid gases with the locations of the BSCP and clay ceramics facilities. The EPA found that only four facilities emitted acid gases within 1 kilometer of any BSCP facility. Beyond 1 kilometer, we would expect very little coincidental impacts from multiple low level sources emitting the same pollutants. The largest of these facilities emitted less than 12 tpy of HCl-equivalent emissions, or less than 5 percent of the emissions limit. The estimated HI for this BSCP facility was 0.6, so an increase of 5 percent in emissions

would result in an increase in HI of at most 5 percent and, thus, not increase the HI above a value of 1. There are no other sources emitting acid gases within 1 kilometer of any clay ceramics facility.

Also, for the BSCP plant with the highest estimated HI, there are no other acid gas emissions indicated in the NEI within 5 kilometers of the facility. For the clay ceramics plant with the highest estimated HI, there are no other acid gas emissions indicated in the NEI within 10 kilometers of the facility. Thus, we would not expect emissions of acid gases from other sources to contribute significantly at the receptors where the maximum HI occurs due to BSCP or clay ceramic emissions, and the HI at these receptors would not exceed 1.

## 5. Risk Assessment

*Comment:* One commenter stated that the Human Exposure Model (HEM-3) meteorological data used for dispersion calculations was insufficient because it included data for only 1 year (2011) from only 824 meteorological stations. The commenter asserted that this provides a very limited snapshot of air quality data and, therefore, is insufficient to determine with confidence that exposures at the proposed emissions standards pose “no risk” of adverse health effects. The commenter stated that it is unlawful and arbitrary to set CAA section 112(d)(4) standards without more extensive air quality information.

*Response:* The EPA disagrees with the commenter that the meteorological data were insufficient to perform the risk assessment. Although 5 years of meteorological data are preferred for assessing chronic exposures and risks, we use a single year (2011) of meteorological data in our risk assessments because of model run times for the Human Exposure Model (HEM-3) air dispersion model (AERMOD). Because we frequently run AERMOD for an entire source category with many individual emissions points and for many receptors, using 5 years of meteorological data would increase already significant model run times by a factor of five compared to a single year. In a sensitivity analysis of the impact of using a single year of meteorological data compared to 5 years,<sup>87</sup> we found that modeled concentrations differed by less than 10 percent on average and, thus, the use of

<sup>83</sup> U.S. Census Bureau, 2010 Census Urban and Rural Classification and Urban Area Criteria, <https://www.census.gov/geo/reference/ua/urban-rural-2010.html> (revised Feb. 9, 2015) (searching plant location by city listed in address).

<sup>84</sup> Memorandum from Science Advisory Board, U.S. EPA, to Lisa Jackson, Adm’r, U.S. EPA re: Review of EPA’s Draft, EPA-SAB-10-007 at 6 (May 7, 2010).

<sup>85</sup> CalEPA, OEHHA, Cumulative Impacts at 19–21, 25 (describing total “pollution burden” as sum of exposures, public health effects, and environmental effects); EPA, Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects, at 4–42 to 4–46 (Aug. 2007).

<sup>86</sup> Responses to Public Comments on EPA’s National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units, vol. 1, Docket Item No. EPA-HQ-OAR-2009-0234-20126.

<sup>87</sup> U.S. EPA, 2009. Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA’s Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing, EPA-452/R-09-006. Docket Item No. EPA-HQ-OAR-2013-0291-0044.

1 year of meteorological data is not likely to appreciably affect the results of the risk assessment.

The meteorological data we used were obtained from the Automated Surface Observing Systems (ASOS) program, which is a joint effort of the National Weather Service (NWS), the Federal Aviation Administration (FAA), and the Department of Defense (DOD). The ASOS serves as the nation's primary surface weather observing network and is designed to support weather forecast activities and aviation operations and, at the same time, support the needs of the meteorological, hydrological, and climatological research communities. With the largest and most modern complement of weather sensors, ASOS has significantly expanded the amount of available meteorological information. The ASOS works non-stop, updating observations every minute, 24 hours a day, every day of the year. The ASOS is installed at more than 900 airports across the country, and our meteorological library for the year 2011 includes all of these that are without a significant number of missing hours (824 stations).

*Comment:* Two commenters stated that the EPA's modeling understates chronic health risk by assuming that chronic exposure to HAP from BSCP and clay ceramic manufacturing sources occurs at the census block centroid and not at the facility fence or property line. The commenters stated that exposures are likely to be higher for people living closest to the plants, especially because census blocks can cover a large area and the center of a census block is almost always farther away from the facility than the facility's property line. One commenter noted that even if the area near the property line is not developed, over time homes and businesses could locate closer to the facility. While it is possible that population distribution is homogenous over a census block, the commenter stated this assumption is not necessarily accurate in considering the predicted impacts from the location of a source.

One commenter stated that no effort was made to move receptor points closer to the facility to assess chronic or cancer risk, even in those instances where local residents live nearer to a facility than the geographic centroid of the census block. This conflicts with the recommendation of the SAB, which has urged the EPA to consider "specific locations of residences."<sup>88</sup> The

commenter stated that the EPA failed to adjust receptor points for residents living on the fence-line even though the HEM-AERMOD system allows for such an adjustment, and that such an adjustment was appropriately made for the estimation of acute health risks (see, e.g., 79 FR 75644). The commenter stated that the EPA cannot justify failing to analyze chronic health effects in a similar manner.

Another commenter agreed and stated that the EPA can use HEM-3 to identify the maximum individual risk at any point in a census block that is within a 50-kilometer radius from the center of the modeled facility. The commenter recommended the EPA not use the predicted chronic exposures at the census block centroid as a surrogate for the exposure concentrations for all people living in that block; instead, the EPA should use the maximum individual risk in its risk assessments, irrespective of its location in the census block.

*Response:* The EPA disagrees with the commenters' assertion that we relied solely on the census block centroids as receptors for human exposure. As we have noted in the development of RTR regulations, in a national-scale assessment of lifetime inhalation exposures and health risks from facilities in a source category, it is appropriate to identify exposure locations where it may be reasonably expected that an individual will spend a majority of his or her lifetime. Further, in determining chronic risks, it is appropriate to use census block information on where people actually reside, rather than points on a fenceline, to locate the estimation of exposures and risks to individuals living near such facilities.

Census blocks are the finest resolution available as part of the nationwide population data (as developed by the U.S. Census Bureau); each is typically comprised of approximately 50 people, or about 20 households. In the EPA risk assessments, the geographic centroid of each census block containing at least one person is used to represent the location where all the people in that census block live. The census block centroid with the highest estimated exposure then becomes the location of maximum exposure, and the entire population of that census block is assumed to experience the maximum individual risk. In some cases, because actual residence locations may be closer

to or farther from facility emission points, this may result in an overestimate or underestimate of the actual annual concentrations (although there is no systematic bias for average levels). Given the relatively small dimensions of census blocks in densely populated areas, there is little uncertainty introduced by using the census block centroids in lieu of actual residence locations. There is the potential for more uncertainty when census blocks are larger, although there is still no systematic bias. The EPA concludes that the most appropriate locations at which to estimate chronic exposures and risks are the census block centroids because: (1) Census blocks are the finest resolution available in the national census data, (2) facility fencelines do not usually represent locations where chronic exposures are likely and (3) there is no bias introduced into the estimate of the MIR by using census block centroid locations. In addition, in its peer review of the methodologies used to estimate risks as part of the RTR rulemaking efforts, the EPA's SAB endorsed this approach.

In addition to the approach described above, the EPA recognizes that where a census block centroid is located on industrial property or is large and the centroid is less likely to be representative of the block's residential locations, the block centroid may not be the appropriate surrogate. For BSCP facilities, in cases where a census block centroid was within 300 meters of any emission source (and therefore possibly on facility property), we viewed aerial images of the facility to determine whether the block centroid was likely located on facility property. Likewise, we examined aerial images of all large census blocks within 1 kilometer of any emission source. If the block centroid did not represent the residential locations within that block, we relocated it to better represent them and/or we added additional receptors for residences nearer to the facility than the centroid. For this source category, we relocated 14 census blocks that appeared to be on facility property or were otherwise not representative of the population within the block, and we modeled an additional 15 receptors in cases where the single block centroid was inadequate to characterize the population within the census blocks.

*Comment:* One commenter stated that the EPA's risk assessment did not account for the synergistic health effects from the potential exposure to multiple acid gas pollutants. Specifically, the EPA did not demonstrate that no health effects would occur if a person is chronically exposed to a combination of

<sup>88</sup> Memorandum from Science Advisory Board, U.S. EPA, to Lisa Jackson, Administrator, U.S. EPA re: Review of EPA's Draft entitled, "Risk and Technology Review (RTR) Risk Assessment

Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing" at 4. May 7, 2010.

HCl, HF, and Cl<sub>2</sub>, even if the sum of the exposures (converted into “equivalent” units) does not exceed the “HCl-equivalent” limit. The commenter also argued the EPA failed to provide evidence showing that the acid gases would not have synergistic effects that could cause harm at a chronic exposure concentration that is lower than the RfC, REL, or MRL of each pollutant. The commenter asserted the EPA did not seek outside peer review by the SAB or other body or request public comment on its use of dose-response values to exchange exposures of one acid gas pollutant for another prior to proposing use of “HCl-equivalents” standards.

The commenter stated that since the EPA based the ratio for comparing HF and Cl<sub>2</sub> emissions to HCl emissions on the RfC, REL or MRL values, and those values are uncertain and flawed (see previous comments in this section V.A, explaining that values were not based on a NOAEL, and the EPA has “low” confidence in the HCl RfC), the HCl-equivalent method cannot assure “an ample margin of safety.” The commenter asserted that CAA section 112(d)(4) requires the EPA to set separate standards for HCl and HF, and the EPA’s decision to set a HCl-equivalent emissions standard is unlawful and arbitrary.

*Response:* The EPA believes that groups of chemicals can behave antagonistically or synergistically, such that combined exposure can either cause less or more harm, depending on the chemicals. To address pollutant mixtures in the determination of the HBEL, the EPA generally used the same methodology used in RTR assessments, which is to follow the EPA’s mixture guidelines.<sup>89 90</sup> This methodology has been formally peer reviewed by the SAB.<sup>91</sup> Following the mixture guidelines, the EPA aggregated noncancer hazard quotients (HQs) of HAP that act by similar toxic modes of action or that affect the same target organ. This process creates, for each target organ, a target-organ-specific hazard index (TOSHI), defined as the sum of HQs for individual HAP that

affect the same organ or organ system. All TOSHI calculations were based exclusively on effects occurring at the “critical dose” (*i.e.*, the lowest dose that produces adverse health effects). The EPA actually calculated the HBEL conservatively by including HF in the calculation of equivalent emissions even though it affects a different target organ than HCl and Cl<sub>2</sub>, thereby allowing the development of a single emissions limit for all acid gases. The conservatism in the limit due to the inclusion of pollutants with different target organ systems would have the effect of ameliorating potential synergism of the acid gases.

#### 6. Ample Margin of Safety

*Comment:* One commenter disagreed with the EPA’s decision to set an HCl-equivalent HBEL, rather than set separate HBEL for HCl, HF, and Cl<sub>2</sub>. The commenter stated that, by setting one “HCl-equivalent emissions” limit at 250 tpy (57 lb/hr) for BSCP tunnel kilns and 600 tpy (140 lb/hr) for clay ceramics sources, each source is free to emit whatever combination of HCl, HF, and Cl<sub>2</sub> it would like, provided the aggregate of the “HCl-equivalent emissions” does not exceed the limit. The commenter also noted that the HCl-equivalent HBEL for clay ceramics does not include Cl<sub>2</sub> and requested that the EPA explain how it converted Cl<sub>2</sub> into HCl-equivalent emissions.

The commenter stated that CAA section 112(d)(2) mandates that the EPA “shall require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section.” The commenter asserted that it is unlawful for the EPA not to set an emissions limit for a CAA section 112-listed pollutant (*Nat’l Lime Ass’n*, 233 F.3d at 634) and concluded that even if the EPA believes the health risks posed by HF and Cl<sub>2</sub> emissions can be translated into HCl-equivalent units, the proposed “HCl-equivalent” limit contravenes the EPA’s obligation to set CAA section 112(d) standards for each pollutant.

The commenter also stated that the EPA’s approach raises questions about whether the use of “HCl-equivalents” results in limits that protect people against all of a pollutant’s health risks with “an ample margin of safety,” as required by CAA section 112(d)(4). The commenter argued that because pollutants cause different adverse health effects, they are not “equivalent” pollutants that cause “equivalent” health effects at “equivalent” concentrations of exposure. The commenter further argued the RfC for HCl is based on a study of respiratory

toxicity and is meant to protect individuals against respiratory harms from chronic exposures, while the REL used for HF is based on a study of skeletal fluorosis (increased bone density) and is meant to protect individuals against skeletal harm from chronic exposures.<sup>92</sup> The commenter noted that the EPA focused only on the respiratory harm caused by the pollutants, when skeletal harm is the most sensitive effect for HF, and the EPA failed to explain why skeletal harm caused by a certain quantity of HF can be converted into respiratory harm caused by HCl.

The commenter also noted that the EPA does not claim to be using HCl as a surrogate for HF or Cl<sub>2</sub>. The commenter stated that the EPA previously stated that HCl cannot act as a surrogate for the other acid gases because pollutants that act on humans in different manners, at different doses, cannot stand in for one another (see 76 FR 25049 and 75 FR 32031).

Another commenter expressed concern the HCl-equivalent emissions limit could mask exposures or emissions of concern for the most toxic gas because the comparison would be dominated by a higher concentration pertinent to the less toxic gases. The commenter asserted that there is no analysis that justifies this combined metric and noted it would be more justifiable if the substances were in the same order of magnitude for potential potency. The commenter recommended that the EPA consider whether these gases could contribute to the acid component of ambient air that is thought to potentially contribute to cancer and other effects because these impacts appear not to have been considered by the EPA.

*Response:* The EPA disagrees with the commenters’ assertion that the HBEL cannot be based on equivalent emissions of a single pollutant. For the BSCP Manufacturing rulemaking, the EPA used an approach specific for this NESHAP to set health-protective emissions limits that would account for the multiple acid gas pollutants emitted by the BSCP facilities. By converting the emissions of each acid gas or combination of acid gases (HCl, Cl<sub>2</sub> and

<sup>89</sup> U.S. EPA, 1986. Guidelines for the Health Risk Assessment of Chemical Mixtures. EPA-630-R-98-002. September 1986.

<sup>90</sup> U.S. EPA, 2000. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. August 2000.

<sup>91</sup> U.S. EPA Science Advisory Board, 2010. Review of EPA’s draft entitled, “Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA’s Science Advisory Board with Case Studies—MACT 1 Petroleum Refining Sources and Portland Cement Manufacturing.” May 7, 2010. Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/\\$File/EPA-SAB-10-007-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf).

<sup>92</sup> OEHA, Chronic RELs and Toxicity Summaries, at 278. CalEPA made it clear that its REL is for “[i]ncreased bone density (skeletal fluorosis),” that the NOAEL was for “chronic skeletal fluorosis,” and that “[c]hanges in bone density . . . appear[s] to be the most sensitive health effect for chronic exposure.” OEHA, Chronic RELs and Toxicity Summaries at 272, 278-79. The principal study on which the REL is based did observe an increase in the incidence of acute respiratory disease, too, *id.* at 271, but the REL was not primarily based on that health effect.

HF) to an HCl-equivalent emission, the EPA can estimate a single exposure concentrations for comparison with the HCl reference value (RfC). If the ratio of HCl exposure concentration to the HCl RfC value remains at or below 1, the HBEL (HCl-equivalent emissions) would ensure that the threshold values for any individual or combination of acid gases would not be exceeded (*i.e.*, remain at or below 1). The EPA used the same approach to convert emissions of HF to an HCl-equivalent and determine the HBEL for the Clay Ceramics Manufacturing NESHAP; the only difference is that there are no valid Cl<sub>2</sub> emissions data for clay ceramics facilities, so Cl<sub>2</sub> is not included in the HBEL.

*Comment:* Two commenters generally supported the proposed HBEL and stated that the EPA has conclusively demonstrated that the proposed HBEL would provide an ample margin of safety for HCl, HF, and Cl<sub>2</sub> emissions from affected facilities. As the EPA explained in the proposal, the analysis was based on site specific data from each tunnel kiln, and the proposed HBEL was developed at a level that would result in an HQ of 1 at the worst-case facility. Because the potential risks at facilities other than the worst-case facility are predicted to be well below 1, the commenters stated that this analysis assures that an ample margin of safety will be provided for the “worst case” facility in the industry and more than an ample margin will be provided for all other affected facilities.

Conversely, another commenter contended that the EPA’s proposed HBEL under CAA section 112(d)(4) does not include “an ample margin of safety.” The commenter disagreed with the approach the EPA used to determine the CAA section 112(d)(4) limits. Specifically, the commenter stated that by setting the limits at precisely the same level as the threshold value, the EPA proposed to allow plants to emit acid gas pollution that would expose people to amounts of pollution that reach threshold levels.

The commenter stated that these limits do not include any “margin of safety,” let alone an “ample” one, as the EPA is required to include for CAA section 112(d)(4) standards. The commenter expressed concern that under the EPA’s approach, even the slightest uncertainty in the EPA’s estimates or low background levels of pollution can place health at risk because plants can emit at the health threshold. The commenter stated that the EPA did not explain how these limits would protect public health with

“an ample margin of safety.”<sup>93</sup> The commenter asserted that a margin of safety is supposed to provide additional safety and account for uncertainty and variability that might result in harm to individuals below the threshold. The commenter further stated that an “ample” margin of safety must assure not only extra room for safety, but a “generous” margin for safety.<sup>94</sup>

The commenter noted that a TOSHI (which is the sum of the HQs) of “one” does not necessarily represent a safe level of exposure. The commenter asserted the EPA characterizes a TOSHI or HQ of “one” or less as exposures that “are not likely to cause adverse health effects” (79 FR 75643), but did not provide any explanation why this level would meet the statutory standard. According to the commenter, Congress intended the standard to be set at a level at which there is “no risk” of “adverse health effects,” plus “an ample margin of safety (and not considering cost).”<sup>95</sup> For these reasons, the commenter concluded that the proposed limits do not comply with the CAA and could put public health at risk.

The commenter also expressed concern that the EPA did not take steps to adjust the limits to reflect the uncertainties regarding health exposures and effects. The EPA has factored in uncertainties and vulnerability factors in other rulemakings, such as when determining a Target Margin of Exposure under the FQPA, where the EPA considered whether risks below the Target Margin of Exposure warranted increased scrutiny and changes to allowable exposures.<sup>96</sup> The commenter also stated that the EPA’s proposed limits would allow human exposures to exceed the level that CalEPA has identified is the safety minimum. Allowing human exposure to HCl concentrations above a threshold a state agency determined may cause respiratory harm, the commenter contended, would not provide the ample margin of safety required by law.

The commenter further stated that the “ample margin of safety” language in CAA section 112(d)(4) requires that any

<sup>93</sup> *Mountain Commc’ns v. FCC*, 355 F.3d 644, 648–49 (D.C. Cir. 2004) (agency must “explain how its position can be reconciled” with statutory requirements).

<sup>94</sup> Webster’s Seventh New Collegiate Dictionary (1971) defines “margin” as “a spare amount or measure or degree allowed or given for contingencies or special situations” and “ample” as “generous or more than adequate in size, scope, or capacity.”

<sup>95</sup> S. Rep. No. 101–228, at 171.

<sup>96</sup> See, *e.g.*, EPA, Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, Proposed Rule, 76 FR 3422, 3427 (Jan. 19, 2011) (explaining use of MOE).

standard that is set under this authority must be sufficient to protect against significant unforeseen consequences.<sup>97</sup> The commenter stated that because the “ample margin of safety” requirement is meant to protect against risks that have not yet been identified in research, a CAA section 112(d)(4) standard cannot be justified on grounds that the EPA does not have sufficient evidence about the health risks posed by a HAP or does not have the time or inclination to review the evidence that is available.

*Response:* For several reasons, the EPA disagrees with the commenter who stated that the HBEL does not include an ample margin of safety. First, the limit is based on the single facility in the source category with the worst-case combination of meteorology and distance to nearest residential receptor that leads to the highest ambient concentrations. While the EPA estimates that the limit reflects an HI of one at this facility, the HI at most other facilities would be significantly lower, with approximately 90 percent of the facilities having an estimated HI less than or equal to 0.5. Further as the standard is based on a 1-hour emission limit, in determining chronic impacts, the analysis conservatively assumes that each plant emits at the 1-hour HBEL for an entire year (8,760 hours). Also, the limit is based on estimated ambient concentrations and not exposure concentrations. Exposure concentrations are typically lower than ambient concentrations because they reflect that people’s activities (*e.g.*, work, school) remove them from their residential exposure locations for significant amounts of time. For these reasons, the EPA concludes that the emission limit is health protective (*i.e.*, exposures will remain below the threshold values) and this conservative exposure scenario is consistent with the “ample margin of safety” requirement in CAA section 112(d)(4).

*Comment:* One commenter expressed concern that the EPA underestimated acute health risks in the evaluation of the risk of acute harm from short-term exposures by ignoring variability in short-term emissions. The commenter noted that the EPA calculated the 1-hour emissions estimates for its modeling of acute harm by dividing the annual emissions level by 8,760 hours per year instead of using a default factor or emissions multiplier to account for higher-than-average short-term

<sup>97</sup> See, *e.g.*, *Env’tl. Def. Fund v. EPA*, 598 F.2d 62, 81 (D.C. Cir. 1978) (holding that the phrase ‘ample margin of safety’ in the Clean Water Act’s toxic provisions required the EPA to protect against as yet unidentified risks to human health, including those “which research has not yet identified”).



emissions. The commenter noted actual emissions over a 1-hour period will at times exceed the average hourly emissions level used in the modeling. The commenter asserted the EPA did not explain how this approach captures peak short-term emissions levels or adequately protects people from short-term exposures at levels above the average.

The commenter stated that the EPA has used emissions multipliers to scale up average hourly emissions in air dispersion modeling for other risk assessments.<sup>98</sup> The commenter asserted that although emission multipliers in risk assessments still underestimate risk, these assessments show the EPA recognizes the need to use multipliers in assessing health risks from short-term emissions. The commenter stated that it is unlawful and arbitrary for the EPA not to use an emissions multiplier for estimating risk for this rulemaking.

The commenter also stated that the EPA's calculation of 1-hour emissions assumed plants are operating (and generating emissions) 24 hours per day, 365 days per year. The commenter noted that averaging hourly emissions over the full calendar year produces lower hourly emissions than if the EPA had used each plant's actual operating hours. The EPA has information about each plant's operating hours and these data show many units are not operating over the full calendar year. By calculating the 1-hour emissions based on 8,760 operating hours, the commenter asserted the EPA underestimated the risks of acute exposures over shorter spans of time.

The commenter stated that because the EPA used short-term emissions that are neither conservative nor realistic, the EPA cannot conclude the standard assures "an ample margin of safety." The commenter stated that in two other

recent rulemakings, the EPA found information on short-term HCl emissions was insufficient to allow the EPA to evaluate "whether a chronic health-based emission standard for HCl would ensure that acute exposures will not pose any health concerns." (75 FR 32031; 76 FR 25050). In these rulemakings, the commenter stated, the EPA did not proceed with risk-based standards due to the lack of this information. The commenter stated that the EPA is incorrectly proceeding with the proposed health-based standards without accounting for or quantifying peak short-term emissions.

*Response:* The use of an emissions multiplier to convert annual emissions to peak 1-hour emissions (determination of peak emissions for comparison with 1-hour health benchmarks) for acute (short-term) risk calculations was not necessary for this analysis, because the HBEL determined for the category is being promulgated as a mass of HCl-equivalent emitted per hour. Similarly, plant hours of operation need not be considered because the HBEL determined for the category is an hourly limit. As noted in the preamble to the proposed rule for BSCP, "To assure that no source emits more than the 250 tpy HCl-equivalent limit in a single hour, we propose setting the emissions limit at the hourly equivalent of 250 tpy (57 lb/hr of HCl-equivalent emissions)" (79 FR 75644). Similarly, for clay ceramics manufacturing, "to assure that no source emits more than the 600 tpy HCl-equivalent limit in a single hour, we propose setting the emissions limit at the hourly equivalent of 600 tpy (140 lb/hr of HCl-equivalent emissions)" (79 FR 75661).

The EPA concludes the risk analysis and subsequent standard meet an "ample margin of safety" in accordance with the CAA. The proposed HBEL for the entire source category is based on an emissions level corresponding to a maximum noncancer HI of one at the highest impacted facility. All other facilities would have a lower risk than the highest risk facility. Further, as the standard is based on a 1-hour emission limit, in determining chronic impacts, the analysis conservatively assumes that each plant emits at the 1-hour HBEL for an entire year (8,760 hours).

*Comment:* One commenter disagreed with the EPA's evaluation of acute health risks, stating that the approach is inadequate and does not assure standards are based on a safe health threshold and include "an ample margin of safety." Specifically, the commenter expressed concern that the proposed HBEL are based on the chronic dose-response information and

not on thresholds for acute health risks. The commenter noted the EPA approximated exposures, used those estimates to develop HQ values, and concluded "there is low potential for acute risk" when the HQ values are less than or equal to one. If values above one were identified, then the EPA examined additional information to determine whether there was a potential for "significant acute risks" for those living near the facility. The commenter noted that the EPA did not explain why this method satisfies the CAA section 112(d)(4) requirement that health-based standards be set at a level that ensures "an ample margin of safety" for people living near the facility. The EPA's evaluation is designed to determine whether any facilities pose "significant acute risks"; however, the commenter stated that this is not the statutory standard, and such a determination would not signify that an "ample margin of safety" is included.

The commenter stated that for HF, the EPA's evaluation identified numerous plants at which there were potential acute health risks. Specifically, the EPA found 23 BSCP facilities exceeded the HQ value for HF, with nearly half of those facilities exceeding the value by four- or five-fold. For the clay ceramics category, the EPA found that eight facilities exceeded the HQ value for HF. The additional analysis the EPA performed to determine whether these facilities posed "significant acute risks" did not rule out the possibility of such "significant acute risks." For these facilities, the EPA focused its analysis on maximum offsite HQ values; however, the commenter noted that many of the maximum offsite HQ values exceed one, thereby indicating the potential for "significant acute risks" remained. The commenter asserted that the EPA provided no support for why values above one means there is no potential for "significant acute risks."

The commenter disagreed with the EPA's assertion that there is no potential for "significant acute risks" because the risk assessment assumes there is a person present at the location and time where the maximum HQ value occurs and stated that relaxing conservative assumptions about exposure in individual instances is arbitrary and defeats the purpose of the evaluation. The EPA cannot pretend that the person is not present and ignore the potential for harm. The EPA's statement that a facility is not likely to emit only HF similarly provides no assurance of safety. According to the commenter, the EPA relaxed an assumption in the model because the model predicted an outcome the EPA did not like. The

<sup>98</sup> See, e.g., National Emission Standards for Hazardous Air Pollutant Emissions: Group IV Polymers and Resins; Pesticide Ingredient Production; and Polyether Polyols Production; Proposed Rule, 77 FR 1268, 1279 (Jan. 9, 2012) (finalized at 79 FR 17340 (Mar. 27, 2014)); see also National Emission Standards for Hazardous Air Pollutants: Ferroalloys Production, 79 FR 60238, 60252 (Oct. 6, 2014) (applying "an emission adjustment factor" to "average annual hourly emission rates . . . to account for emission fluctuations due to normal facility operations"); National Emissions Standards for Hazardous Air Pollutants Residual Risk and Technology Review for Flexible Polyurethane Foam Production, 78 FR 66108, 66122 (Nov. 4, 2013) (applying "a conservative default emissions multiplier of 10 to estimate the peak hourly emission rates from the average rates" as part of EPA's screening of "worst-case acute impacts"); National Emissions Standards for Hazardous Air Pollutants: Mineral Wool Production and Wool Fiberglass Manufacturing, 76 FR 72770, 72785 (Nov. 25, 2011) (applying an "emissions multiplier of 3 to estimate the peak hourly emission rates from the average rates").

commenter stated the EPA provided no basis for its assertion that a facility is unlikely to emit only HF or explain why a combination of HF (for which the EPA found a potential for “significant acute risks”), HCl, and Cl<sub>2</sub> emissions would not still pose “significant acute risks.”

The commenter stated that the EPA’s use of acute exposure guideline levels (AEGLs) and emergency response planning guidelines (ERPGs) to assess acute risks cannot assure that exposure presents “no risk” of health effects at those concentrations. The AEGL and ERPG values were created for emergency exposure scenarios. The commenter stated that levels defined for “once-in-a-lifetime, short-term exposures” and “emergency” chemical releases or accidents are not appropriate for measuring acute exposure risk. According to the SAB, indicated “AEGL–2 and ERPG–2 values should never be used in residual risk assessments because they represent levels that if exceeded could cause serious or irreversible health effects.”<sup>99</sup>

The commenter stated that because the AEGL and ERPG numbers would underestimate risk to the maximum exposed individual, AEGL and ERPG values do not indicate “safe” thresholds that protect health with “an ample margin of safety.” For these reasons, the commenter contends AEGL and ERPG values should not be used to set CAA section 112(d)(4) standards.

*Response:* The EPA disagrees with the commenter that the EPA’s acute assessment includes arbitrary decision-making and does not reflect an ample margin of safety. The EPA is not required to regulate based solely on the results of a conservative acute screening scenario which assumes that a person will be present at a specific location and during worst-case meteorological conditions. Rather, this initial screening scenario is used as a starting point in the assessment of the potential for acute effects.

For HCl and Cl<sub>2</sub>, the acute REL values for the pollutants are not estimated to be exceeded even when using the screening scenario, and the acute REL for HF is estimated to be exceeded only by a factor of two for seven facilities using the screening scenario. The other cases of higher exceedances mentioned by the commenter are situations where the locations of the exceedances are on facility property and, therefore, not considered for public health. The acute REL is defined by CalEPA as “the concentration level at or below which no adverse health effects are anticipated

for a specified exposure duration. RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of uncertainty factors which are incorporated to address data gaps and uncertainties.

Regarding the use of AEGL and ERPG values, the EPA does not rely exclusively upon these values for assessment of acute exposures. Rather, the EPA’s approach is to consider various acute health effect reference values, including the California REL, in assessing the potential for risks from acute exposures. To better characterize the potential health risks associated with estimated acute exposures to HAP, and in response to a key recommendation from the SAB’s peer review of the EPA’s RTR risk assessment methodologies, we generally examine a wider range of available acute health metrics (e.g., RELs, AEGLs) than we do for our chronic risk assessments. This is in response to the SAB’s acknowledgement that there are generally more data gaps and inconsistencies in acute reference values than there are in chronic reference values. In some cases, when Reference Value Arrays<sup>100</sup> for HAP have been developed, we consider additional acute values (i.e., occupational and international values) to provide a more complete risk characterization. Because HCl, HF, and Cl<sub>2</sub> all have 1-hour REL values, the maximum estimated 1-hour concentrations were compared to these values to assess the potential for acute health effects.

*Comment:* One commenter expressed concern that the EPA’s risk analysis ignored exposures from emissions of HCl, HF, Cl<sub>2</sub>, and other pollutants with similar biological endpoints from units subject to the proposed work practice standards, including emissions during startup and shutdown, and emissions from BSCP periodic kilns and sanitaryware shuttle kilns. The commenter asserted that even though the EPA stated that the work practice standards are intended to minimize emissions, these sources are not included in the calculation of the CAA section 112(d)(4) standards, and exposures to emissions from these other

sources will contribute to an individual’s cumulative health risks. The commenter asserted that the EPA does not know whether the proposed HBEL will provide “an ample margin of safety” once emissions from periods of startup and shutdown and emissions from BSCP periodic kilns and sanitaryware shuttle kilns are added to the levels of pollution permitted by the proposed standards. For this reason, the commenter stated that the proposed CAA section 112(d)(4) standards are unlawful and arbitrary.

The commenter also stated that emissions during startup and shutdown are expected to be uncontrolled, because the EPA did not propose to require that BSCP and clay ceramics plants use APCD or other methods to reduce emissions (such as mandating the use of clean fuels) during these periods. The proposed work practice standards for periodic and shuttle kilns do not require control technology and, according to the commenter, are not anticipated to reduce emissions.

Finally, the commenter stated that the only reason startup and shutdown periods and periodic and shuttle kilns are not subject to the proposed CAA section 112(d)(4) limits is because the EPA exempted them from CAA section 112(d). The commenter stated that it is arbitrary to exclude those emissions from the health analysis solely because the EPA proposed to regulate those sources of emissions under a different subsection of the CAA. The commenter argued all exposures contribute to the risk of harm, regardless of whether they are CAA section 112(d)-regulated emissions or section CAA 112(h)-regulated emissions.

*Response:* The EPA disagrees that emissions during periods of startup and shutdown and emissions from BSCP periodic kilns and sanitaryware shuttle kilns will exceed the numerical HBEL. Regarding the standards for periods of startup and shutdown, as noted in the preamble to the proposed rule and further documented in Docket ID No. EPA–HQ–OAR–2013–0291,<sup>101</sup> temperature is the main factor affecting full production at BSCP plants. The kiln cars should be introduced into the kiln at a steadily increasing push rate to facilitate development of that specific kiln’s firing temperature profile. Since emissions are generated from the firing of the bricks and the fuel combusted, the EPA has concluded that the maximum magnitude of emissions will occur when all kiln cars have been

<sup>99</sup> Memorandum from Science Advisory Board re: Review of EPA’s Draft at 6.

<sup>100</sup> U.S. EPA. (2009) Chapter 2.9 Chemical Specific Reference Values for Formaldehyde in Graphical Arrays of Chemical-Specific Health Effect Reference Values for Inhalation Exposures (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–09/061, and available on-line at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=211003>.

<sup>101</sup> Email from Susan Miller, BIA, to Sharon Nizich and Keith Barnett, EPA. “Additional documents.” Dated June 25, 2015.

loaded with the maximum number of bricks and the maximum amount of fuel is used. During startup, kiln operators will limit production until the kiln has heated enough to begin normal operation. This is the point whereby the standard transitions from a work practice to a numeric limit. The opposite process occurs during shutdown. Fuel use will decrease significantly so as to cool the kiln, and kiln operators will slow production to a stop. Since emissions will be lower below this point of maximum loading and fuel use, emissions will not rise above the emission limit for all pollutants, including the acid gas limits.

The owner or operator of each kiln will be required to determine the startup production rate for the kiln. For kilns with an APCD, the owner or operator will determine the minimum inlet temperature for the APCD. For kilns that, through compliance testing once the compliance date has been reached, have shown they are emitting under the emission limits and thus do not have an APCD, the owner or operator will determine the product-specific kiln temperature profile that must be achieved before the kiln can reach full production. The startup standards will be tied to the startup production rate never being exceeded until the kiln reaches the minimum inlet temperature for the APCD or the product-specific kiln temperature profile, whichever is applicable. During shutdown, once the kiln falls below the minimum inlet temperature for the APCD or the product-specific kiln temperature profile, whichever is applicable, no additional product can be introduced. These temperature limits will be required to be included in the facility's records and kept on site. Thus, for periods of startup and shutdown, the HBEL set for HCl, HF, and Cl<sub>2</sub> will not be surpassed during startup and shutdown.

In the case of sanitaryware shuttle kilns, the commenter is mistaken that we did not mandate the use of clean fuels. The rule does limit the fuels used to natural gas or equivalent, and also outlines work practice standards relative to temperature cycles and maintenance procedures designed to minimize HAP emissions (see Table 3 to subpart KKKKK). The use of clean fuels applies for all times the kiln is running, not just startup and shutdown. Therefore, the commenter is incorrect that we are not requiring the use of clean fuels for startup and shutdown relative to the operation of shuttle kilns.

The EPA also disagrees that just because the proposed work practice standards for periodic and shuttle kilns

do not reflect the use of any control technology, they are not anticipated to reduce emissions. As the commenter has stated elsewhere, control technologies are not the only means of limiting emissions. Control of parameters such as fuel, operating temperature, combustion conditions, and throughput are also effective means of limiting emissions, and these are the types of parameters the EPA considered when finalizing the work practice standards for periodic and shuttle kilns.

As discussed in the proposal at 79 FR 75662, CAA section 112(h)(1) states that the Administrator may prescribe a work practice standard or other requirements, consistent with the provisions of CAA sections 112(d) or (f), in those cases where, in the judgment of the Administrator, it is not feasible to enforce an emission standard. Section 112(h)(2)(B) of the CAA further defines the term "not feasible" in this context to apply when "the application of measurement technology to a particular class of sources is not practicable due to technological and economic limitations," which is the case here. There are fewer BSCP periodic kilns and first-fire sanitaryware shuttle kilns compared to tunnel kilns, and they tend to be low-emitting sources compared to tunnel kilns,<sup>102</sup> so their emissions will not cause an exceedance of the health threshold. The work practice standards we are finalizing will serve to ensure that emissions from these sources continue to remain low.

*Comment:* One commenter stated that, to create standards that assure "an ample margin of safety," the EPA is required to build a margin into the HBEL for exposures to HCl, HF, Cl<sub>2</sub>, and other pollutants with similar biological endpoints resulting from (a) exceedances of the HCl, HF, and Cl<sub>2</sub> standards, (b) violations of the work practice standards applicable during startup and shutdown, and (c) exceedances of other standards (e.g., MACT standards for non-Hg HAP

<sup>102</sup> For example, even assuming that lb/ton emissions are similar for BSCP periodic and tunnel kilns, a comparison of annual kiln design capacities (ton product/yr) for model BSCP periodic kilns and tunnel kilns indicates that annual capacities for periodic kilns are on average only 5 percent of annual capacities for tunnel kilns. (For the basis of this calculation, see the memorandum "Updated Inventory Database and Documentation for Brick and Structural Clay Products Manufacturing Final Rule" in Docket ID No. EPA-HQ-OAR-2013-0291 and the memorandum "Final Rule: Documentation of Database and Responses to the 1997 Information Collection Request for Brick and Structural Clay Products" in Docket ID No. A-99-30.) In addition, in the BSCP industry, there are currently 120 periodic kilns located at 15 facilities, compared to 168 tunnel kilns at 84 facilities. In the sanitaryware industry sector, there are currently five first-fire shuttle kilns, compared to 11 first-fire tunnel kilns.

metals) that restrict pollutants with similar biological endpoints. The commenter also stated that estimating short-term emissions by averaging annual emissions does not reflect emissions spikes that occur during plant malfunctions or upsets. The commenter stated that malfunctions and upsets increase emissions and thereby pose increased health risks that the EPA must consider.

The commenter stated that relevant chronic exposures include exposures from exceedances and violations and noted that many exceedances, such as those from malfunctions and upsets, are likely to contribute significant emissions that can elevate an individual's total exposures over time. The commenter also stated that the EPA explains malfunction events can be significantly higher than emissions at any other time of source operation (79 FR 75626). The commenter stated that these emissions pose much higher short-term risks and can accumulate and combine to increase public health impacts and risk and that guarding against the health risks of releases of large amounts of HF (for example) must be built into the HBEL through the margin of safety. The commenter stated that HF exhibits characteristics in some circumstances that can make it uniquely hazardous over large areas. For example, HF molecules may associate with one another (*i.e.*, form larger molecules like H<sub>4</sub>F<sub>4</sub>, H<sub>6</sub>F<sub>6</sub>, H<sub>8</sub>F<sub>8</sub>) via hydrogen bonding and such molecules may form a cloud that is heavier than air, therefore less likely to disperse.

The commenter stated that, by not accounting for exposures from exceedances, the EPA assumed that such exceedances will be zero and built in no additional protections in case exceedances do occur. The commenter claimed that there is no factual basis for assuming that 100 percent of BSCP and clay ceramics facilities will comply with each of the relevant emissions limits 100 percent of the time. Over the long term and across the population of regulated facilities, the commenter noted that it is predictable that a number of exceedances will occur at facilities. The commenter stated it is unlawful to ignore emissions and the resulting health risks from those exceedances and argued the additional risk from exceedances should not be ignored in risk assessments.

The commenter stated that EPA regularly uses statistical methods and probability factors to assess health risk due to exceedances and to set clean air standards, and the EPA has data available to calculate representative factors to assess the health risk from

malfunctions or can collect information on major sources' malfunction and violation histories.<sup>103</sup> If the EPA needs more refined data regarding these emissions, the commenter suggested the EPA may request additional data from sources.

The commenter stated that it is irrelevant that exceedances are a result of a failure to comply with the law when the EPA is setting CAA section 112(d)(4) standards, which must be set at a level that protects health. It does not matter to a person whether the pollution he or she is breathing is a result of a permitted or unpermitted release; the commenter argued the EPA cannot turn a blind eye to the reality that compliance with its standards is not perfect.

*Response:* The HBEL was determined based on the assessment of acute effects at the worst-case facility with respect to meteorology and distance to receptor and is protective of most facilities even if they had SSM event emissions. Even for the worst-case facility, the SSM emissions event would need to be coincident with the worst-case meteorological conditions, which is not likely if SSM events are not frequent. For chronic risk, SSM emissions are not significant compared to the HBEL level, and most facilities are well below an HI of one with emissions at the HBEL level.

The commenter is correct that the EPA did not include malfunctions and upsets emissions in setting emissions limits. As noted in the preamble to the proposed rule (79 FR 75626), malfunctions "are, by definition sudden, infrequent and not reasonably preventable failures of emissions control, process or monitoring equipment." The preamble also stated that "accounting for malfunctions in setting emission standards would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree and duration of various malfunctions that might occur. For these reasons, the performance of units that are malfunctioning is not 'reasonably' foreseeable." It should also be noted that sources cannot conduct performance tests during periods of malfunction (40 CFR 63.8445(e) and 40 CFR 63.8595(d)) and there are no continuous emissions monitoring systems (CEMS) in place in the BSCP industry.

The EPA disagrees that it is required to evaluate the ample margin of safety provided by a CAA section 112(d)(4) standard based on the level of emissions that could occur during an exceedance of the standard caused by a malfunction or any other cause. When the EPA establishes a standard under CAA section 112(d)(4), the EPA evaluates the ample margin of safety based on what sources will emit when they are meeting the standard (which applies at all times including periods of malfunction) and does *not* include some additional margin of safety to compensate for periods of time that sources may violate the standard. This is consistent with how the EPA evaluates standards under CAA section 112(f)(2) (in that the EPA's evaluation of the ample margin of safety under that review looks at the emissions allowed under the standard, not emissions that might occur when the standard is exceeded).

Regarding the comment that the standard is not health protective for emissions of HF, the proposed rule determined the HCl equivalent emissions for HF by the ratio of the RfC value for each pollutant, such that a 250 tpy emission of HCl is equivalent to 175 tpy emissions of HF. By performing a risk analysis for each facility/kiln, the EPA demonstrated that these emissions limits are protective of both chronic and acute risks.

Regarding the comment that HF exhibits release characteristics that may make it uniquely hazardous over large areas, the EPA notes that the commenter did not include data or information supporting their assertion that plumes of acid gases from BSCP facilities could become heavier than air. The commenter's example case of the formation of dense clouds of acid gases is from studies performed on the vaporization of liquefied gaseous fuels from spills, and the commenter did not explain how this scenario is relevant to the emission of acid gases formed in BSCP kilns. In the absence of evidence suggesting that clouds of dense gases are formed from BSCP facilities, and without a suggested alternate modeling methodology, the EPA used its preferred model AERMOD for dispersion for BSCP facilities.

#### 7. Other Issues

*Comment:* One commenter stated that the EPA must account for the variability in emissions measured by compliance testing to measure whether each plant's emissions meet the HBEL because that testing does not capture a source's variance in emissions performance over time. The commenter noted that the EPA already recognizes this fact for

stack tests for technology-based standards. The EPA has stated that it lacks a high degree of confidence that stack tests capture variation in emissions over time, and the commenter noted that as a result of this variance, it can be expected that the compliance tests would not be accurate. The commenter asserted that if the EPA believes that measurement variability needs to be corrected for, then it is irrational and arbitrary to correct for it with one set of standards (MACT standards) and not another (health-based standards), when they both rely upon emissions data from stack tests. The commenter noted that the EPA's proposal to account for variability for MACT standards but not for compliance with the HBEL would result in weaker and less-protective standards in both cases.

*Response:* Variability in emissions would not have a significant impact on the estimated risks associated with the HBEL. For chronic exposures and risks, the estimates are based on long-term (annual) emissions, so short-term emissions variability would not impact the estimates of chronic risks as long as the annual emissions, on average, do not exceed the limit. For acute exposures and risks, short-term emissions variability that causes emissions to exceed the 1-hour HBEL would increase the potential for acute health effects, but the likelihood of such effects is low because the emissions variability would have to occur at the small number of facilities we estimated as having the highest acute HQs based on the emissions limits, and the emissions variability would have to coincide with worst-case meteorological conditions even at those facilities to result in acute HQs higher than those we estimated based on the HBEL. Most facilities have acute HQ estimates significantly below one, so short-term emissions variability would have to be high (approximately 60 percent higher for the median facility) for the estimated HQs to approach a value of one.

The EPA also notes that the HBEL was not established using emissions data from stack tests. Therefore, there was no need to account for variability in setting the HBEL as was done for the Hg and non-Hg HAP metals standards. Instead, the standard was established at a conservative level to ensure that the HQs remain below one for all facilities. The EPA agrees that there would be variability in the test results used to demonstrate compliance with the rule, but as already noted in this response, short-term emissions variability would have to be high for the estimated HQs to approach a value of one. In addition,

<sup>103</sup> See, e.g., EPA, Enforcement and Compliance History Online (ECHO), [www.epa.gov/echo](http://www.epa.gov/echo).

variability is not considered when comparing compliance testing results to any other emissions limit, so it would be inconsistent for the EPA to require owners and operators to adjust their test results before comparing those results to the HBEL.

*Comment:* One commenter suggested that the EPA should require fence-line ambient air quality monitoring that measures multiple pollutants in real-time or near real-time to ensure that people are not being exposed to ambient pollutant concentrations that exceed the proposed HBEL. The commenter recommended the EPA also require real-time public reporting of the monitoring data.

In addition, the commenter suggested that the EPA should require facilities to submit monitoring plans, data, and corrective action plans for agency review and public comment. These requirements would ensure concerned community members have the ability to review and recommend improvements to monitoring plans before they are implemented and would enable the EPA to consider community concerns when deciding whether to approve a plan.

*Response:* The EPA disagrees with the commenter. Because stack emissions can travel for long distances and are at heights above where a fence-line monitors would measure, it is inappropriate to use fence-line monitoring for stack emissions. Fence-line monitoring is performed for fugitive emissions (see discussion of fence-line monitoring use on fugitive emissions at 79 FR 36919, Petroleum Refinery Sector Risk and Technology Review and New Source Performance Standards; Proposed Rule). In response to the comment that the EPA should require all facilities to submit monitoring plans, data, and corrective action plans for agency review and public comment, the EPA notes that these requirements are indeed in the rule, as facilities are required to submit monitoring plans, data and corrective actions for the regulatory agency review. However, in most cases, these submissions are required to be sent to the delegated authority, and the follow-up to that review, is left to the discretion of the delegated authority.

## B. BSCP Manufacturing NESHAP

### 1. MACT Floors

#### a. Sources in MACT Floor Pool

One commenter stated that the DC Circuit held that the BSCP Manufacturing NESHAP published on May 16, 2003 (68 FR 26690) violated the CAA in a number of ways (*Sierra Club v. EPA*, 479 F.3d 875 (D.C. Cir. 2007)).

The court held that, in setting MACT floors for brick tunnel kilns, the EPA's exclusion of kilns employing non-DLA controls from its ranking and identification of the best performing sources was unlawful because CAA section 112(d)(3) "requires floors based on the emission level actually achieved by the best performers (those with the lowest emission levels)." *Id.* In addition, the court recognized that factors other than pollution control technology affect performance (*e.g.*, clay type), and the EPA cannot ignore such factors, even where the EPA finds that floors based on those factors would be unachievable.

The commenter noted that the EPA is once again excluding best performing sources from its floor analysis and basing floors on a group of kilns using the EPA's preferred control technologies, in contravention of the holding of *Sierra Club*, which is the decision to which this rulemaking is intended to be a response. In the proposed rule, prior to ranking the best performing sources for the BSCP tunnel kiln floors for PM (as a surrogate for non-Hg HAP metals) for existing and new sources, the EPA removed all kilns without a FF-based APCD. Once removed, those kilns were not included in the ranking of best performing sources, and hence they were not considered for inclusion among the best performing 12 percent of sources (for the existing source floor) or the best controlled similar source (for the new source floor). The commenter asserted that the agency's reprisal of a floor approach that the DC Circuit has already rejected repeatedly is not just unlawful, but amounts to contempt for the court's authority.

*Response:* The EPA disagrees with the commenter's assertion that the EPA's proposed approach to calculating PM surrogate MACT floors for kilns was illegal in that it impermissibly excluded certain kilns. However, at proposal, we asked for comment on this approach and requested additional data to support this approach, and we did not receive any such additional data. In addition, some of the test data for sources with FF-based APCD could not be used in the final rulemaking because it was discovered that the testing was not carried out in accordance with the appropriate test method. Therefore, we can no longer assert that we have emissions data for all BSCP kilns with FF-based APCD. Thus, the EPA did not use the approach challenged by the commenter to establish the MACT floors in the final rule.

The EPA has amended the approach to developing PM surrogate MACT floors for reasons explained in section

IV.A.1 of this preamble, so these comments are now moot. However, the EPA still believes the approach to identify the best performing sources has merit. When the EPA has data on every single controlled source in the category, and these data support that these sources are the best performing, then basing the MACT floor on the top 12 percent of the total number of sources is appropriate.

#### b. Equivalent Limits

*Comment:* One commenter stated that, in addition to the lb/ton MACT floors for emissions of Hg and PM (as a surrogate for non-Hg HAP metals), the EPA developed two "equivalent limits." The EPA used its ranking of the sources based on their "average" lb/ton emissions to identify the best performing source or sources for the floor pool. To develop the PM and Hg "equivalent" limits, the EPA took the best performing source or sources the EPA had selected and retrieved data on those sources' emission performance as measured by gr/dscf at 7-percent O<sub>2</sub> for PM and Hg and lb/hr for Hg. For non-Hg HAP metals, the EPA proposed to set an additional standard that would limit the pounds of non-Hg HAP metals emitted per hour. For this additional limit, the EPA again used the ranking of the sources based on their "average" lb/ton emissions and also (without any explanation) no longer used PM as a surrogate for non-Hg HAP metals, but instead set the limit in terms of total non-Hg HAP metals. The commenter stated that the EPA acknowledged that the available data on non-Hg HAP metals is incomplete, so to develop this proposed limit, the EPA simply took the final pounds of PM per ton of fired product floor limit that it had derived and applied a set of "conversion factors" it invented to put that standard in terms of pounds of non-Hg HAP metal emissions per hour. The commenter stated the EPA used completely different "conversion" methodologies for the new and existing standards because the EPA lacks even the limited data it used for the existing source methodology on new sources.

The commenter stated the "equivalent" limits the EPA proposed are not "equivalent" and Congress did not give the EPA the authority to set multiple limits and allow sources to comply with whichever limit they choose. The commenter stated the EPA's use of different measures of performance to identify the top sources on the one hand and to evaluate their performance on the other is inconsistent, irrational, and unexplained; the same metric should

apply for purposes of identifying the best performers and identifying those sources' actual performance. The commenter also stated the EPA did not use the best performing 12 percent of existing sources "for which the Administrator has emissions information" for the non-Hg HAP metals lb/hr limit.

Another commenter supported the EPA's inclusion of multiple formats for both PM/non-Hg HAP metals and Hg. The commenter stated that the inclusion of each of these formats, as well as the inclusion of small and large kiln subcategories, provides needed flexibility to numerous BSCP facilities, including a large number of small businesses, to find that standard that best suits their operations while still ensuring that the CAA requirements are met. The commenter asserted that the inclusion of three alternate compliance formats is so critical to the development of this standard that the EPA must re-propose this rule if it maintains numeric limits but deletes any of these alternative formats for the final rule.

*Response:* The EPA appreciates all comments regarding the alternative limits. The EPA is retaining the alternative limits in the final rule but is revising the ranking methodology as described in section IV.A.2 of this preamble. For the final rule, the concentration floor is based on the ranking of the concentration data, and the lb/hr floor is based on the ranking of the lb/hr data. Each floor is based on the best performing units for that unit of measurement.

### c. Oxygen Correction

*Comment:* One commenter stated, regarding the concentration compliance limits, that the use of the equation to correct measured concentrations to 7-percent O<sub>2</sub> could be problematic when used to correct concentrations measured in stacks with high O<sub>2</sub> content, which is typical of the brick industry. The commenter stated because the correction term is in the denominator of the equation for the correction to 7-percent O<sub>2</sub>, the overall correction factor increases exponentially as O<sub>2</sub> concentrations approach 20.9 percent. As a result, any variances in the O<sub>2</sub> measurement are greatly magnified in the correction factor for kilns with high stack O<sub>2</sub> content. The commenter suggested that the correction factor should be the average O<sub>2</sub> content represented in the respective floors, 17-percent O<sub>2</sub> (based on a range of O<sub>2</sub> stack contents for BSCP kilns from 13 to 20 percent). The commenter asserted that the correction to an average of 17-

percent will minimize the artificial inflation of the results for the industry.

*Response:* The EPA evaluated the O<sub>2</sub> content of the run-by-run datasets of PM and Hg for BSCP tunnel kilns as described in section IV.A.1 of this preamble and agrees that correcting concentration data to 17-percent O<sub>2</sub> rather than 7-percent, as proposed, provides more representative values of kilns' operating conditions and would not artificially inflate the values. For the final rule, the EPA has taken the O<sub>2</sub> percent analysis into consideration and revised the equivalent concentration based limits to be developed from 17-percent O<sub>2</sub>-corrected concentration data.

### 2. Startup and Shutdown

*Comment:* Numerous commenters supported the use of work practice standards for periods of startup and shutdown but asserted that the startup and shutdown procedures listed in the proposed rule cannot be met by all BSCP kilns and must be modified. Commenters requested that the final language allow a more basic construct for the work practice requirements in the final rule and require facilities to develop site-specific temperatures as part of their permitting process.

Multiple commenters specifically stated that the requirement for an exhaust temperature of 400 °F at startup is not workable because the kiln exhaust temperature in some kilns never reaches 400 °F. Commenters also noted that kilns must have product at startup. Therefore, commenters requested that the startup provisions apply to the introduction, or charging, of new brick or structural clay product through a kiln and not impact the initial staging of kiln cars in a kiln before start-up. Commenters suggested revisions to the proposed language to "not put any bricks into the kiln" below specified temperatures.

Multiple commenters agreed with the language that requires a kiln to vent to an APCD before the exhaust gas reaches 400 °F, because it can vent at any time up to that temperature. Multiple commenters stated that for a controlled kiln, it is acceptable to require that no new product is allowed to be introduced to the controlled kiln until the kiln is vented to an APCD. One commenter stated that a feasible work practice standard would be for the exhaust gases to be vented through the APCD during the startup process, with the reagent feed started on an intermittent basis during this period and then brought up to full feed rate once the exhaust temperature has reached the normal operating temperature range.

A few commenters also requested specific revisions to the production requirements for periods of shutdown. One commenter stated that during shutdown, a kiln operator would not be pushing any cars in the kiln after reaching a range of 250 to 300 °F in the exhaust stack (depending on the type of kiln and its operating parameters). The commenter asked that a minimum operating range be allowed during a shutdown cycle. Another commenter noted that a limitation for a kiln to cease charging in new product before a kiln stops venting to an APCD may be a reasonable alternative to temperature requirements.

*Response:* The EPA evaluated the comments and additional information received following proposal as described in section IV.A.4 of this preamble. As a result, the EPA has revised the work practice standards for periods of startup and shutdown for BSCP tunnel kilns to provide requirements that are more representative of the best performing kilns. Specifically, instead of defining the minimum inlet APCD temperature as 400 °F, the EPA is requiring the owner or operator to determine the minimum inlet temperature for each APCD. If a kiln does not have an APCD, the owner or operator is required to determine the product-specific kiln temperature profile that must be achieved before the kiln can reach full production. In addition, instead of specifying that no product can be introduced to the kiln during startup, the EPA is requiring the owner or operator to determine the production rate needed to start up the kiln. The final startup standards specify that this startup production rate cannot be exceeded until the kiln exhaust reaches the APCD minimum inlet temperature or the product-specific kiln temperature profile, whichever is applicable. The final shutdown standards specify that no additional product can be introduced once the kiln exhaust falls below the APCD minimum inlet temperature or the product-specific kiln temperature profile, whichever is applicable.

### C. Clay Ceramics Manufacturing NESHAP

#### 1. Authority

*Comment:* Two commenters argued that the EPA has no legal authority to finalize major source NESHAP for the ceramic tile manufacturing industry<sup>104</sup>

<sup>104</sup> There are three distinct sectors within the clay ceramics manufacturing industry: ceramic floor tile manufacturing, ceramic wall tile manufacturing, and sanitaryware manufacturing. These comments

because there are currently no existing major sources in that industry sector that will be subject to the standards. Specifically, they argued that CAA section 112(d)(1) only provides the EPA authority to regulate a category or subcategory if it has major sources. Commenters contended that, here, ceramic tile manufacturing facilities that emit HAP have all become synthetic area sources and so are subject to the “area source” NESHAP regulation. Thus, they argue, the law does not allow the EPA to proceed with a major source standard for these subcategories. Both commenters also stated that the CAA does not give the EPA the authority to regulate “just-in-case” there is a major source in the future, and the EPA may only regulate categories and subcategories that currently have major sources in them.

One commenter stated that the EPA should not devote resources to finalizing these regulations when those regulations would apply to no one, and, thus, will have no environmental benefits. The commenter stated that it is the EPA’s duty to responsibly steward the public resources with which it has been entrusted to use in fulfillment of its mission, and using these resources to issue regulations that will regulate no one fails to satisfy that responsibility. Issuing such regulations is expensive for the regulated community and has the real potential to create unintended, inaccurate impressions of the industry, its emissions and its products. It serves no public purpose, and will impose short and long term costs on the EPA, and long term costs on delegated states as an unfunded mandate and on the tile manufacturing industry, 79 FR 75671 (Dec. 18, 2014).

The commenter argued that, because the EPA’s promulgation of standards for the ceramic tile industry is not authorized by the CAA, finalizing such standards would violate Articles I and II of the U.S. Constitution because it is an attempt by the EPA to rewrite portions of the CAA when the power to enact laws is reserved to Congress. The commenter stated that Congress provided clear instructions to the EPA, in the unambiguous numerical definition of “major source,” as to which industry categories or subcategories could be regulated by major source NESHAP standards. The commenter noted that the Supreme Court very recently stated: “An agency may not rewrite clear statutory terms to suit its own sense of how the statute

should operate.” *Util. Air Regulatory Grp. v. EPA*, 134 S.Ct. 2427, 2446 (2014). Further, the Court stated: “We are not willing to stand on the dock and wave goodbye as EPA embarks on a multiyear voyage of discovery.” 134 S.Ct. at 2446. The commenter asserted that the Supreme Court’s concerns in the *UARG* case are instructive here because, as in the *UARG* case, the statute creates unambiguous numeric thresholds defining a major source: the emission of 10 tpy any one HAP or the emission of 25 tpy in the aggregate of all HAP, 42 U.S.C. 9612(a)(1). The commenter contended that the Supreme Court supported the commenter’s position when it stated that “[i]t is hard to imagine a statutory term less ambiguous than the precise numerical thresholds . . .” *Id.* at 2445.

The commenter argued that the *Sierra Club* consent decree is irrelevant to the EPA’s statutory authority and its limitations. The consent decree entered in the case of *Sierra Club v. EPA*, 850 F.2d 300 (D.D.C. 2012) (hereafter the “consent decree”) is germane to the timing of this rulemaking, but it does not, and legally could not, expand CAA section 112(d) to grant the EPA legal authority to regulate on the just-in-case basis the EPA has proposed. The withdrawal of the proposed NESHAP does not preclude the EPA from meeting its statutory obligations, fulfilling the requirements of the consent decree, and continuing its existing precedent. The EPA may issue final NESHAP for those subcategories within this category in which a major source exists. The ceramic tile manufacturing industry is not among them.

The commenter argued that the proposed NESHAP would, if finalized as proposed, be arbitrary and capricious because the proposed NESHAP is based on hypothetical or imaginary manufacturing and air emissions control strategies, flawed data from an invalidated stack test method, and on statistically created emissions data. The EPA even proposed in places not to use actual emissions data.

According to the commenter, the EPA’s proposal, if finalized, would create an economic hurdle so high that no one in the industry would expand their business to the point of becoming a NESHAP major source. Further, a substantial number of these entities meet the definition of a “small business” as defined by the U.S. Small Business Administration (SBA). The result of this regulation, if finalized, would be to hand non-market-based economic advantages to foreign producers to grow their presence in the U.S. market by importing their

competing ceramic tile. Financing of capital projects will be adversely affected by the costs imposed by the NESHAP, further raising the economic hurdle. Major source domestic manufacturing capacity will not be built, and the jobs and tax base that go along with that capacity will not be created.

*Response:* Under CAA section 112(c)(1), the EPA first lists all categories and subcategories of major sources. It is at this first step that the EPA determines that a given category or subcategory contains major sources of HAP. Then, the EPA sets standards for those listed categories and source categories. Both CAA section 112(c)(2) and CAA section 112(d)(1) make clear that the EPA is to regulate all listed categories and subcategories. As CAA section 112(c)(2) states: “For the categories and subcategories the Administrator lists, the Administrator shall establish standards . . .” As CAA section 112(d)(1) states: “The Administrator shall promulgate regulations establishing emissions standards for each category and subcategory of major sources and area sources of hazardous air pollutants listed for regulation pursuant to subsection (c) of this section . . .” In short, once a category or subcategory of major sources is listed under CAA section 112(c), it must be regulated. If commenters believe that the major source ceramic tile subcategories should not be regulated, they may seek to delete these subcategories from the list, which is a process that Congress established in CAA section 112(c)(9) and which the DC Circuit has held is the EPA’s sole authority for removing a listed category or subcategory from the list. *New Jersey v. EPA*, 517 F.3d 574, 581–583 (D.C. Cir. 2008).

In interpreting the relevant provisions here, the EPA is mindful of the recent and longstanding instructions from the Supreme Court that statutory provisions must be read to further rather than undermine Congress’s statutory intent. *King v. Burwell*, 2015 U.S. Lexis 4248, \*29 (2015) (“We cannot interpret federal statutes to negate their own stated purposes.”)(citing and quoting *New York State Dept. of Social Servs. v. Dublino*, 413 U. S. 405, 419–420, 93 S. Ct. 2507, 37 L. Ed. 2d 688 (1973)); *E.I. Du Pont De Nemours v. Train*, 430 U.S. 112, 132 (1977) (“We cannot, in these circumstances, conclude that Congress has given authority inadequate to achieve with reasonable effectiveness the purposes for which it has acted.”)(quoting *Permian Basin Area Rate Cases*, 390 U.S. 747, 777 (1968)). In this context, it is unreasonable to read

address the regulation of HAP emissions from ceramic floor tile manufacturing and ceramic wall tile manufacturing.



CAA section 112(d)(1) as limiting the EPA's authority to set standards that will be applicable to the highest emitting sources in a category or subcategory and creating a loophole by which major sources can evade regulation. Without suggesting that the following is the commenters' intent, the effect of the commenters' interpretation of CAA section 112 would be that major sources would be able to evade regulation by, first, becoming synthetic area sources during the rulemaking process (which, under the commenters' view, would preclude the EPA from finalizing standards for major sources) and then, after the EPA withdraws the proposed standards, reconvert to be major sources and thus not subject to any standard. Consideration of this scenario is particularly appropriate in the circumstances here, because there are standards in place for area sources in the ceramic tile subcategories. It is not reasonable to interpret CAA section 112 to create a structure where an area source (whether a natural area source or a synthetic area source) has an incentive to increase emissions to become a major source, and by doing so is no longer subject to emissions limitations.

Further, the issue of whether there are major sources in the ceramic tile subcategories is not as clear as the commenters presume. Even if, as the commenters contend, all of the existing major sources in these subcategories have successfully completed the process of becoming synthetic area sources, then these sources are not subject to the requirements imposed on major sources but that does not equate to a conclusion that they are no longer major sources in any respect. The EPA's view is that synthetic area sources, though subject to area source requirements rather than major source requirements, are still major sources in certain respects. For example, synthetic area sources are considered to be major sources when the EPA identifies the best performing major sources as part of a MACT floor calculation under CAA section 112(d). Further, CAA section 112(a)(1) defines a major source as "any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants." The reference to a source's "potential to emit considering controls" in this definition allows the interpretation that a source's potential to emit before and after controls is

relevant, such that synthetic area sources may be considered within the meaning of this definition.

With respect to the commenter's argument that CAA section 112 does not authorize "just in case" regulation, that is both not correct and off point. First, CAA section 112 clearly provides that the EPA will set standards for new sources in the listed categories and subcategories notwithstanding that the EPA can never know whether there will actually be any new sources. As required under CAA section 112, the EPA establishes new source standards "just in case" (to use commenter's phrasing) new sources come into existence. Second, as discussed above, it is reasonable for the EPA to promulgate major source standards where, as here, there are synthetic area sources that could revert to major sources just in case that happens.

With respect to the commenters' argument that it is a poor use of agency resources for the EPA to finalize standards for the ceramic tile subcategories, the EPA has considered whether it is better to complete the current rulemaking with respect to the ceramic tile subcategories (and have them in place in the event that there are new major sources or a synthetic area source reverts to major source status) or to take no action now and re-do this rulemaking with respect to these subcategories in the event that there are major sources in the future. The EPA's conclusion is that, having gotten this far along in the rulemaking process, it is a better use of agency resources to finalize requirements for the ceramic tile subcategories now. Given the options, finalizing these requirements in this rulemaking requires only a modest amount of additional resources, and is a much more efficient use of agency resources than restarting and repeating the rulemaking process at some point in the future. Even if one considers that there may not be any major sources that become subject to these requirements and that such a rulemaking might not ever be done, the EPA's judgment is still that it is more efficient and a more cost-effective use of agency resources to finalize these requirements now. Finally, on the issue of how likely it is that major sources will be built in the future, the EPA notes that the commenters' own arguments suggest they will be. Specifically, the commenters stated that having a major source standard in place will dissuade companies from expanding small facilities into major sources and will impede financing for new major sources. The premise of such a comment is that, in the absence of a standard,

there will be such expansions and new major sources.

The document "National Emission Standards for Hazardous Air Pollutants for Clay Ceramics Manufacturing: Background Information for Final Rule—Summary of Public Comments and Responses" in Docket ID No. EPA-HQ-OAR-2013-0290 addresses additional comments on this topic.

*Comment:* According to one commenter, the EPA failed to demonstrate that the benefits of this proposed arbitrary and capricious NESHAP justify the costs. As stated in Executive Order 13563, "Improving Regulation and Regulatory Review," issued by President Obama on January 18, 2011 to reaffirm Executive Order 12866, "[e]ach agency must . . . propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs." The preamble to the proposed NESHAP provides cost information (which the commenter noted elsewhere is erroneous) but did not discuss the benefits. The EPA only articulated the benefits of the BSCP Manufacturing NESHAP. With respect to costs, the EPA's cost analysis failed to account for costs to the agency and delegated states to promulgate and implement the regulations. There are no benefits to justify any of these costs. Further, "[i]n deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating." The EPA did not assess the alternative of not regulating—a path that would have exactly the same result, as there are no major sources to be regulated or not regulated. Therefore, the commenter stated that the EPA failed to meet its burden; the proposed NESHAP does not have benefits justifying its costs, and therefore such a regulation cannot be adopted.

*Response:* We disagree with the commenter. First, CAA section 112 clearly states that the EPA is obligated to regulate emissions of HAP from listed source categories. There is no benefits test in the statutory requirement. The language in Executive Order 12866 does not supersede a clear legal requirement in the CAA. Second, because there are no major sources that will be regulated by this rule at the present time, there will be no implementation costs for the rule. If at a later date a major source is constructed, or a non-major source becomes major, then there will be implementation costs, but this rule will result in emission reduction requirements compared to the emissions that would be expected to occur in the absence of a rule. Therefore, at the point

where this rule actually results in costs, it will also have corresponding benefits. In the absence of any current major sources that will be covered by this rule, we simply cannot calculate the benefits.

## 2. MACT Floors

*Comment:* One commenter disagreed with the inclusion of emissions data from Kohler's South Carolina facility tunnel kiln with the wet scrubber in the sanitaryware tunnel kiln existing source data pool for MACT floor determination. The commenter stated that Kohler installed a new tunnel kiln at the South Carolina facility in 2005 under the Clay Ceramics Manufacturing NESHAP promulgated in 2003, which, according to the commenter, required the installation of APCD on any new first-fire tunnel kilns to meet the HF and HCl emission limitations. The APCD that Kohler installed, a wet scrubber, was written into the facility's air permit at the time, and so its use at that time was federally enforceable. The court vacated the Clay Ceramics Manufacturing NESHAP in 2007, and the South Carolina Department of Health and Environmental Control revised the facility's air permit in March 2009, removing any reference to the Clay Ceramics Manufacturing NESHAP and any requirement to operate the scrubber. Kohler then permanently shut down the scrubber in March 2009, though they continued to operate the tunnel kiln per permit requirements. Due to cost considerations, the scrubber was abandoned in place and not demolished/removed.

The commenter noted that, when the EPA issued the information collection request (ICR) for clay ceramics emissions test data in 2010, the EPA required that Kohler make operational that wet scrubber for emissions testing of that tunnel kiln, even though the APCD was not listed in any permit nor required under any rule and had not been operated in 17 months. Initially, Kohler agreed to test the kiln as an existing source per operational requirements in the facility's air permit (*i.e.*, without the wet scrubber). However, the EPA demanded that Kohler restart and operate the abandoned scrubber during the kiln's emissions testing. The commenter noted that Kohler cooperated with the EPA and tested emissions with the scrubber operating, but the scrubber was immediately shut down after testing. This scrubber has operated for a total of 1 week in the past 6 years, and that short period of operation was only to comply with the EPA's ICR testing demand.

The commenter acknowledged that the EPA has the authority require operation of any permitted source for emissions testing under rulemaking and ICR protocol. The commenter agreed with the EPA that the "kiln" in question is an existing source but disagreed that the non-operating wet scrubber qualifies as part of an existing source. The commenter contended that the EPA is arbitrarily penalizing Kohler for not spending the money to demolish and remove the wet scrubber back in 2009 when it was removed from the facility's air permit. The commenter asserted that the test data from the wet scrubber are not representative of any existing source and were not actually achieved in practice over time. Therefore, using the test data in the MACT floor analysis is inconsistent with the EPA's expressed intent to determine MACT floors for existing sources based on the average emissions actually achieved in practice by the best performing sources with consideration for variability in emissions over time. The commenter asserted that all emissions data from the wet scrubber should be excluded from the existing source data pool for MACT floor analysis, and the existing source floors should be recalculated for the remaining existing sources.

*Response:* Data from the APCD the commenter refers to was considered in developing both the new and existing MACT floors for sanitaryware kilns. As stated by the commenter, the APCD was installed to comply with the previously promulgated Clay Ceramics Manufacturing NESHAP and thus was an available data point for collection through the CAA section 114 data collection process for this rulemaking. Because this source had an operational APCD (even though it was not being operated), we believe that testing with the APCD operating would be most representative of the source's best performance as defined in the CAA. Having collected the emissions data for the source with the APCD operating, the EPA considered the data consistent with section 112(d)(3)(B) of the CAA, under which the Administrator is required to calculate "the average emission limitation achieved by the best performing 5 sources (for which the Administrator has or could reasonably obtain emissions information) in the category or subcategory for categories or subcategories with fewer than 30 sources." Since it is appropriate to include the data in the database available to determine MACT floors, it is appropriate to use these data in floor calculations, if it is actually part of the best performing facilities. We note,

however, that the data from this device was only significant for the existing source dioxin/furan MACT floor, for reasons that are dependent on each regulated pollutant and discussed as follows.

For both new and existing PM MACT floors, the final limit was unaffected by use of these data, since the data from the APCD was not ranked in the top five sources with data.

For both new and existing Hg MACT floors, the data from the APCD were not ranked because the data were invalidated. The data were removed from the dataset because of errors in the analytical procedures surrounding the digestion process as dictated by Method 29. See Section 4.1: Analytical discrepancy of the Test Report "Kohler Co., Spartanburg, SC: Tunnel Kilns and Glaze Spray Booths 08/11-17/2010 Stack Test," Docket Item No. EPA-HQ-OAR-2013-0290-0069.

For dioxin/furan, the data from the APCD are in the top five but is not the best performing unit based on the dioxin/furan ng/kg ranking. (Note the units of measure for dioxin/furan ranking have changed from the proposed ng/dscm at 7-percent O<sub>2</sub> to ng/kg.) For the existing source floor, the result of the calculation of the best performing five sources is 3.3 ng/kg with the data point, and would have been 4.0 ng/kg without the data point, which we consider a nominal difference. The difference does not result in any source having to add controls. The calculation of the new source floor was not affected by the data from the APCD because, as stated above, the source was not the best performing unit, and the new source floor is based on the best performing unit.

*Comment:* Three commenters questioned EPA's decision to propose the dioxin/furan emission limits for ceramic tile manufacturing and sanitaryware manufacturing in concentration format only. Two commenters stated that the final dioxin/furan standards should provide the option to comply with a limitation expressed in units of nanograms per milligram of tile produced, in addition to or in lieu of the proposed standard stated in ng/dscm. A mass-based production-related standard effectively removed the issues around O<sub>2</sub> correction created by use of a standard based only on concentration. Further, the commenters asserted that it is a more universally appropriate adjustment for comparison of emissions from large kilns having high air flow rates to emissions from small kilns with low air volumes. The third commenter agreed and noted that the proposed

limits for PM and Hg are expressed as lb/ton fired product. The commenter asked EPA to explain how the concentration format for the emission limit is more appropriate for dioxins/furans than a mass throughput limit. If it is not, the commenter suggested using a mass throughput format for the dioxin/furan emission limit.

*Response:* The dioxin/furan limits provided in the final rule for clay ceramics are in units of ng TEQ/kg of throughput fired or processed. The EPA agrees that this change in format eliminates the questions surrounding the O<sub>2</sub> correction for concentration values and is more consistent with the other units of measure provided in the Clay Ceramics Manufacturing NESHAP. To demonstrate compliance with the limits, the owner or operator will determine the mass TEQ for each test run (using the toxic equivalency factors in Table 5 to subpart KKKKK), divide the mass TEQ by the production rate during the test run, and average the test runs.

The production-based dioxin/furan limits are provided in lieu of the proposed concentration limits. The compliance flexibility provided to the BSCP Manufacturing source category (including alternative compliance options for PM and Hg) was solely related to concerns under the Small Business Regulatory Enforcement Fairness Act (SBREFA), specifically reducing the regulatory burden of the numerous small entities in the BSCP category. There are no small businesses expected to be subject to the Clay Ceramics Manufacturing NESHAP, so the EPA determined that no additional compliance flexibility was necessary or warranted for the Clay Ceramics Manufacturing source category.

### 3. Startup and Shutdown

*Comment:* One commenter challenged the proposed startup and shutdown regulations for ceramic tile manufacturing. The commenter asserted that these standards are based conceptually on the desire to minimize the time during which ceramic tile manufacturing process units operate in a temperature range that is “conductive” to the formation of new dioxins/furans (*i.e.*, 200–450 degrees Celsius). The commenter stated that this concern is moot because there are no new dioxins/furans formed in the ceramic tile industry sector, based on the emissions data the EPA proposed to use to set MACT floors for ceramic tile sources and on the fact that ceramic tile dioxin/furan congener profiles are different from the profile of the dioxins/furans created as a product of combustion.

The commenter also challenged the EPA’s startup and shutdown proposal for spray dryers relative to dioxins/furans. The input to the spray dryer experiences no more than 212 °F because the operational purpose of the spray dryer is to cause the excess moisture suspended or attached to the ball clay matrix to evaporate. If any spray dryer operating temperature is relevant to the EPA’s concern about temperatures in a spray dryer conducive to dioxin/furan formation, this is the correct focus.

For ceramic tile floor tile and wall tile roller kilns, the commenter stated that the proposed temperature requirements for startup and shutdown reflect good kiln production practices; therefore, the proposed startup and shutdown standards are unnecessary.

The commenter noted that the standards are based only on data from the BSCP subcategory, and the proposed temperatures are not appropriate for all sources. For example, ceramic tile dryers uniformly operate below 400 °F, so product could never be introduced to a tile dryer. The commenter also noted that the startup provisions require startup of APCD at 400 °F. However, ceramic tile dryers do not have APCD because they burn only natural gas, their normal operating temperature is less than 400 °F, and their resulting emissions are minimal. For these reasons, the proposal effectively constitutes a ban on the operation of tile dryers. If tile dryers are not an available manufacturing process, ceramic tile manufacturing as it is currently conducted in the United States would effectively cease at major sources. The commenter stated that the EPA lacks the legal authority to implement a de facto shut down of major sources, or to bar the possibility of the proposal of a major source, in this industry.

For all the above reasons, the commenter asserted that the EPA must withdraw the startup and shutdown proposal from any final NESHAP for this subcategory. The commenter contended that, as proposed, these standards are arbitrary and capricious.

*Response:* The CAA requires that NESHAP emissions limitations under section 112 must apply continuously, including during periods of startup and shutdown. As noted in the preamble to the proposed rule, we recognize that it is not feasible to conduct emission testing during periods of startup and shutdown; therefore, owners and operators would be unable to demonstrate compliance with the final numeric MACT standards during those periods. Therefore, the EPA is finalizing work practice standards for periods of

startup or shutdown to ensure that the Clay Ceramics Manufacturing NESHAP includes continuous CAA section 112-compliant standards.

The commenter is correct that the specific startup and shutdown work practice standards proposed were based on information from the BSCP industry. In absence of any data on specific startup and shutdown procedures from the clay ceramics CAA section 114 survey, the EPA used the only data available for a similar industry. The EPA has not received any additional information from clay ceramics manufacturers on specific procedures, and in light of that lack of data, the EPA maintains that the less prescriptive startup and shutdown work practices being finalized for the BSCP industry are appropriate for the clay ceramics industry. First, one of the commenter’s main points is that the specific temperatures that were proposed are not appropriate for all the types of units to which the standards were proposed to apply, which is consistent with comments received on the BSCP proposal. Second, the commenter did note that the proposed standards reflect good kiln production practices for one type of process unit for which the specific temperature was appropriate. Therefore, the EPA is finalizing work practice standards that are based on best practices but are less prescriptive than the proposed standards.

As a final note, the EPA is clarifying in this response that the startup and shutdown standards are not intended to minimize only emissions of dioxins/furans. Instead, the standards are intended to minimize emissions of all pollutants by limiting the amount of throughput being processed before the unit reaches full production and limiting the amount of time the exhaust is not being routed to the APCD, if applicable. In addition, the proposed startup and shutdown work practice requirements did not require the use of an APCD, nor do the final standards. The standards only specify the requirements for routing exhaust to an APCD if one is present. The EPA has reviewed the language in the final rule to ensure the standards are clear.

## VI. Summary of the Cost, Environmental, Energy and Economic Impacts

### A. What are the cost and emissions reduction impacts?

Table 8 of this preamble illustrates the costs and emissions reductions for existing sources under the final BSCP Manufacturing NESHAP and final Clay Ceramics Manufacturing NESHAP. The

costs include the costs of installing and monitoring needed to demonstrate APCD as well as the costs for the testing compliance.

TABLE 8—SUMMARY OF COSTS AND EMISSIONS REDUCTIONS FOR BSCP AND CLAY CERAMICS EXISTING SOURCES <sup>a</sup> [2011 dollars]

Industry	Cost (million)		Emissions reductions (tpy)							
	Capital	Annual	HF	HCl	Cl <sub>2</sub>	Non-Hg HAP metals <sup>b</sup>	Hg	PM	PM <sub>2.5</sub> <sup>c</sup>	SO <sub>2</sub>
BSCP .....	\$64.6	\$24.6	344	22.1	2.04	7.08	0.0733	643	309	205
Clay Ceramics .....	0.267	0.0924	0	0	0	0	0	0	0	0

<sup>a</sup> Includes costs for APCD, testing and monitoring.  
<sup>b</sup> Includes antimony, arsenic, beryllium, cadmium, chromium, cobalt, lead, manganese, nickel and selenium.  
<sup>c</sup> PM<sub>2.5</sub> = particulate matter with particles less than 2.5 micrometers in diameter.

The nationwide capital and annual costs of the APCD, testing, and monitoring needed to comply with the final BSCP Manufacturing NESHAP are expected to total \$64.6 million and \$24.6 million, respectively (2011 dollars). The nationwide HAP emissions reductions achieved under the final BSCP Manufacturing NESHAP are expected to total 375 tpy. The methodology used to estimate the nationwide costs and emissions reductions of the final BSCP Manufacturing NESHAP is presented in the technical memoranda titled “Development of Cost and Emission Reduction Impacts for the Final BSCP Manufacturing NESHAP” and “Monitoring and Testing Requirements and Costs for the Final BSCP

Manufacturing NESHAP” in Docket ID No. EPA–HQ–OAR–2013–0291. It is anticipated that all sanitaryware emission points will meet the MACT floor emission limits in the final Clay Ceramics Manufacturing NESHAP, so no emission control costs or emissions reductions are expected for these sources. However, these facilities are expected to incur \$92,400 annually in monitoring and testing costs to demonstrate compliance with the final Clay Ceramics Manufacturing NESHAP. These costs are documented in the technical memorandum titled, “Monitoring and Testing Requirements and Costs for the Final Clay Ceramics Manufacturing NESHAP” in Docket ID No. EPA–HQ–OAR–2013–0290. There are no major sources producing ceramic floor tile or ceramic wall tile.

The five facilities that were major sources at the time of the 2008 and 2010 EPA surveys have already taken the necessary steps to become synthetic area sources. Consequently, none of the known tile facilities will be subject to the provisions of the Clay Ceramics Manufacturing NESHAP, which means that no costs or emissions reductions are expected for tile affected sources under the final Clay Ceramics Manufacturing NESHAP.

*B. What are the secondary impacts?*

Table 9 of this preamble illustrates the secondary impacts for existing sources under the BSCP Manufacturing NESHAP and Clay Ceramics Manufacturing NESHAP.

TABLE 9—SUMMARY OF SECONDARY IMPACTS FOR BSCP AND CLAY CERAMICS EXISTING SOURCES <sup>a</sup>

Industry	Secondary air emissions (tpy)						Energy impacts (MMBtu/yr)	Solid waste impacts (tpy)
	PM	PM <sub>2.5</sub>	CO	NO <sub>x</sub>	SO <sub>2</sub>	CO <sub>2</sub>		
BSCP .....	3.40	1.14	5.74	45.6	133	27,900	461,000	5,210
Clay Ceramics .....	0	0	0	0	0	0	0	0

<sup>a</sup> CO = carbon monoxide; CO<sub>2</sub> = carbon dioxide; MMBtu/yr = million British thermal units per year.

The relevant secondary impacts that were evaluated for the BSCP Manufacturing NESHAP and Clay Ceramics Manufacturing NESHAP include secondary air emissions, energy impacts and solid waste impacts. Indirect or secondary air emissions are impacts that result from the increased electricity usage associated with the operation of APCD to meet the promulgated limits (i.e., increased secondary emissions of criteria pollutants from power plants). Energy impacts consist of the electricity needed to operate the APCD, and solid waste impacts consist of the particulate captured by the APCD that is disposed of as waste (not reused or recycled).

Under the final BSCP Manufacturing NESHAP, the nationwide secondary emissions of the criteria pollutants PM,

CO, NO<sub>x</sub> and SO<sub>2</sub> are expected to total 188 tpy, and secondary emissions of the greenhouse gas pollutant CO<sub>2</sub> are expected to total 27,900 tpy, with energy impacts of 461,000 MMBtu/yr and solid waste impacts of 5,210 tpy. The methodology used to estimate the nationwide secondary impacts of the final BSCP Manufacturing NESHAP is presented in the technical memorandum, “Development of Cost and Emission Reduction Impacts for the Final BSCP Manufacturing NESHAP” in Docket ID No. EPA–HQ–OAR–2013–0291.

As noted in the previous section, it is anticipated that all sanitaryware emission points will meet the MACT floor emission limits in the Clay Ceramics Manufacturing final rule, so there are no secondary impacts expected

for these sources. There are no major sources producing ceramic floor tile or ceramic wall tile. The five facilities that were major sources at the time of the 2008 and 2010 EPA surveys have already taken the necessary steps to become synthetic area sources. Consequently, none of the known ceramic tile facilities are expected to be subject to the provisions of the Clay Ceramics Manufacturing NESHAP, which means that no secondary impacts are expected for ceramic tile affected sources under the final Clay Ceramics Manufacturing NESHAP.

*C. What are the economic impacts?*

For the BSCP Manufacturing source category, the average national brick price under the promulgated standards increases by 1.8 percent or \$4.37 per

1,000 Standard Brick Equivalent (SBE) (2011 dollars), while overall domestic production falls by 1.5 percent or 52 million bricks per year. Under the promulgated standards, the EPA estimated that two to four BSCP manufacturing facilities are at significant risk of closure.

Based on the results of the small entity screening analysis for BSCP Manufacturing, the EPA concluded that it is not able to certify that the BSCP Manufacturing NESHAP will not have a significant impact on a substantial number of small entities. As a result, the EPA initiated a Small Business Advocacy Review (SBAR) Panel and undertook an Initial Regulatory Flexibility Analysis (IRFA).

For Clay Ceramics Manufacturing, one sanitaryware company owns major sources and will incur costs (for testing, monitoring, recordkeeping and reporting). That affected company is not a small business. The compliance costs are less than 0.002 percent of sales for the affected company. Hence, the

economic impact for compliance is minimal. As noted above, there are no major sources producing ceramic floor tile or ceramic wall tile. Because no small firms face significant control costs, there is no significant impact on small entities. Thus, the Clay Ceramics Manufacturing regulation is not expected to have significant impact on a substantial number of small entities.

For more information on the benefits analysis and market analyses, please refer to the Regulatory Impact Analysis (RIA) for the BSCP Manufacturing NESHAP, "Regulatory Impact Analysis: Final Brick and Structural Clay Products NESHAP," which is available in Docket ID No. EPA-HQ-OAR-2013-0291.

*D. What are the benefits?*

Emission controls installed to meet the requirements of this rule will generate benefits by reducing emissions of HAP as well as criteria pollutants and their precursors, NO<sub>x</sub> and SO<sub>2</sub>. Sulfur dioxide and NO<sub>x</sub> are precursors to PM<sub>2.5</sub>, and NO<sub>x</sub> is a precursor to ozone.

The criteria pollutant benefits are considered co-benefits for this rule. For this rule, we were only able to quantify the health co-benefits associated with reduced exposure to PM<sub>2.5</sub> from changes in emissions directly emitted PM<sub>2.5</sub>, SO<sub>2</sub>, and NO<sub>x</sub>. We estimate the monetized co-benefits of the BSCP Manufacturing NESHAP in 2018 to be \$83 million to \$190 million (2011 dollars) at a 3-percent discount rate and \$75 million to \$170 million (2011 dollars) at a 7-percent discount rate, not including consideration of energy disbenefits. Using alternate relationships between PM<sub>2.5</sub> and premature mortality supplied by experts, higher and lower co-benefits estimates are plausible, but most of the expert-based estimates fall between these two estimates.<sup>105</sup> A summary of the emission reduction and monetized co-benefits estimates for this BSCP Manufacturing NESHAP at discount rates of 3 percent and 7 percent is illustrated in Table 10 of this preamble.

TABLE 10—SUMMARY OF THE MONETIZED PM<sub>2.5</sub> CO-BENEFITS FOR THE BSCP MANUFACTURING NESHAP IN 2018  
[Millions of 2011 dollars]<sup>a b</sup>

Pollutant	Emission reductions (tpy)	Total monetized co-benefits (3 percent discount)	Total monetized co-benefits (7 percent discount)
Directly emitted PM <sub>2.5</sub> .....	308	\$83 to \$190 .....	\$75 to \$170.
PM <sub>2.5</sub> precursors			
SO <sub>2</sub> .....	72	\$2.9 to \$6.6 .....	\$2.6 to \$6.0.
NO <sub>x</sub> <sup>c</sup> .....	-46	-\$0.29 to -\$0.66 .....	-\$0.26 to -\$0.59.
Total monetized benefits .....		\$84 to \$190 .....	\$76 to \$170.

<sup>a</sup>All estimates are for the analysis year and are rounded to two significant figures so numbers may not sum across rows. The total monetized co-benefits reflect the human health benefits associated with reducing exposure to PM<sub>2.5</sub> through reductions of PM<sub>2.5</sub> precursors, such as SO<sub>2</sub> and directly emitted PM<sub>2.5</sub>. It is important to note that the monetized co-benefits do not include reduced health effects from exposure to HAP, direct exposure to nitrogen dioxide (NO<sub>2</sub>), exposure to ozone, ecosystem effects or visibility impairment.

<sup>b</sup>PM co-benefits are shown as a range from Krewski, *et al.* (2009) to Lepeule, *et al.* (2012). These models assume that all fine particles, regardless of their chemical composition, are equally potent in causing premature mortality because the scientific evidence is not yet sufficient to allow differentiation of effects estimates by particle type.

<sup>c</sup>These emission reductions are the net emission reductions from the rule after subtracting out secondary emission increases due to additional energy requirements to run the control equipment. These estimates do not include monetized CO<sub>2</sub> disbenefits, which range from \$0.3 to \$3 million depending on the discount rate. See the RIA for more information about how the EPA monetized these disbenefits.

These co-benefits estimates represent the total monetized human health benefits for populations exposed to less PM<sub>2.5</sub> from controls installed to reduce air pollutants in order to meet this rule. Due to analytical limitations, it was not possible to conduct air quality modeling for this rule. Instead, we used a "benefit-per-ton" approach to estimate the benefits of this rulemaking. To create the benefit-per-ton estimates, this

approach uses a model to convert emissions of PM<sub>2.5</sub> precursors into changes in ambient PM<sub>2.5</sub> levels and another model to estimate the changes in human health associated with that change in air quality, which are then divided by the emissions in specific sectors. These benefit-per-ton estimates were derived using the approach published in Fann, *et al.* (2012),<sup>106</sup> but they have since been updated to reflect

the studies and population data in the 2012 p.m. National Ambient Air Quality Standards (NAAQS) RIA.<sup>107</sup> Specifically, we multiplied the benefit-per-ton estimates from the "Non-EGU Point other" category by the corresponding emission reductions.<sup>108</sup> All national-average benefit-per-ton estimates reflect the geographic distribution of the modeled emissions, which may not exactly match the

<sup>105</sup>Roman, *et al.*, 2008. "Expert Judgment Assessment of the Mortality Impact of Changes in Ambient Fine Particulate Matter in the U.S.," *Environ. Sci. Technol.*, 42, 7, 2268–2274.

<sup>106</sup>Fann, N., K.R. Baker and C.M. Fulcher. 2012. "Characterizing the PM<sub>2.5</sub>-related health benefits of emission reductions for 17 industrial, area and

mobile emission sectors across the U.S." *Environment International* 49 41–151.

<sup>107</sup>U.S. Environmental Protection Agency (U.S. EPA). 2012. *Regulatory Impact Analysis for the Final Revisions to the National Ambient Air Quality Standards for Particulate Matter*. EPA-452/R-12-003. Office of Air Quality Planning and Standards,

Health and Environmental Impacts Division. December. Available at <http://www.epa.gov/pm/2012/finalria.pdf>.

<sup>108</sup>U.S. Environmental Protection Agency. 2013. *Technical support document: Estimating the benefit per ton of reducing PM<sub>2.5</sub> precursors from 17 sectors*. Research Triangle Park, NC. January.

emission reductions in this rulemaking and, thus, they may not reflect the local variability in population density, meteorology, exposure, baseline health incidence rates or other local factors for any specific location. More information regarding the derivation of the benefit-per-ton estimates for this category is available in the technical support document, which is available as Docket Item No. EPA-HQ-OAR-2013-0291-0089.

These models assume that all fine particles, regardless of their chemical composition, are equally potent in causing premature mortality because the scientific evidence is not yet sufficient to allow differentiation of effects estimates by particle type. Even though we assume that all fine particles have equivalent health effects, the benefit-per-ton estimates vary between precursors depending on the location and magnitude of their impact on PM<sub>2.5</sub> levels, which drive population exposure.

It is important to note that the magnitude of the PM<sub>2.5</sub> co-benefits is largely driven by the concentration response function for premature mortality. We cite two key empirical studies, one based on the American Cancer Society cohort study<sup>109</sup> and the extended Six Cities cohort study.<sup>110</sup> In the RIA for the final rule, which is available in Docket ID No. EPA-HQ-OAR-2013-0291, we also include benefits estimates derived from expert judgments (Roman, *et al.*, 2008) as a characterization of uncertainty regarding the PM<sub>2.5</sub>-mortality relationship.

Considering a substantial body of published scientific literature, reflecting thousands of epidemiology, toxicology and clinical studies, the EPA's *Integrated Science Assessment for Particulate Matter*<sup>111</sup> documents the association between elevated PM<sub>2.5</sub> concentrations and adverse health effects, including increased premature mortality. This assessment, which was twice reviewed by the EPA's

independent SAB, concluded that the scientific literature consistently finds that a no-threshold model most adequately portrays the PM-mortality concentration-response relationship. Therefore, in this analysis, the EPA assumes that the health impact function for fine particles is without a threshold.

In general, we are more confident in the magnitude of the risks we estimate from simulated PM<sub>2.5</sub> concentrations that coincide with the bulk of the observed PM concentrations in the epidemiological studies that are used to estimate the benefits. Likewise, we are less confident in the risk we estimate from simulated PM<sub>2.5</sub> concentrations that fall below the bulk of the observed data in these studies. Concentration benchmark analyses (*e.g.*, lowest measured level (LML) or one standard deviation below the mean of the air quality data in the study) allow readers to determine the portion of population exposed to annual mean PM<sub>2.5</sub> levels at or above different concentrations, which provides some insight into the level of uncertainty in the estimated PM<sub>2.5</sub> mortality benefits. There are uncertainties inherent in identifying any particular point at which our confidence in reported associations becomes appreciably less and the scientific evidence provides no clear dividing line. However, the EPA does not view these concentration benchmarks as a concentration threshold below which we would not quantify health benefits of air quality improvements.

For this analysis, policy-specific air quality data are not available due to time and resource limitations and, thus, we are unable to estimate the percentage of premature mortality associated with this specific rule's emission reductions at each PM<sub>2.5</sub> level. As a surrogate measure of mortality impacts, we provide the percentage of the population exposed at each PM<sub>2.5</sub> level using the source apportionment modeling used to calculate the benefit-per-ton estimates for this sector. Using the Krewski, *et al.* (2009) study, 93 percent of the population is exposed to annual mean PM<sub>2.5</sub> levels at or above the LML of 5.8 µg/m<sup>3</sup>. Using the Lepeule, *et al.* (2012) study, 67 percent of the population is exposed above the LML of 8 µg/m<sup>3</sup>. It is important to note that baseline exposure is only one parameter in the health impact function, along with baseline incidence rates, population and change in air quality. Therefore, caution is warranted when interpreting the LML assessment for this rule because these results are not consistent with results from rules that model changes in air quality.

Every benefit analysis examining the potential effects of a change in environmental protection requirements is limited, to some extent, by data gaps, model capabilities (such as geographic coverage) and uncertainties in the underlying scientific and economic studies used to configure the benefit and cost models. Despite these uncertainties, we believe the benefit analysis for this rule provides a reasonable indication of the expected health benefits of the rulemaking under a set of reasonable assumptions. This analysis does not include the type of detailed uncertainty assessment found in the 2012 PM<sub>2.5</sub> NAAQS RIA<sup>112</sup> because we lack the necessary air quality input and monitoring data to run the benefits model. In addition, we have not conducted air quality modeling for this rule, and using a benefit-per-ton approach adds another important source of uncertainty to the benefits estimates. The 2012 PM<sub>2.5</sub> NAAQS benefits analysis provides an indication of the sensitivity of our results to various assumptions.

It should be noted that the monetized co-benefits estimates provided above do not include benefits from several important benefit categories, including exposure to HAP, NO<sub>x</sub> and ozone exposure, as well as ecosystem effects and visibility impairment. Although we do not have sufficient information or modeling available to provide monetized estimates for this rule, we include a qualitative assessment of these unquantified benefits in the RIA for these promulgated standards.

The specific control technologies for this rule are anticipated to have minor secondary disbenefits, including an increase of 41 tons of NO<sub>x</sub>, about 3 tons of PM, less than 6 tons of CO and 121 tons of SO<sub>2</sub> each year. Because we do not currently have methods to monetize emission changes of CO, only secondary effects of PM, SO<sub>2</sub>, and NO<sub>x</sub> were included in the monetary evaluation of the actual benefits.

For more information on the benefits analysis, please refer to the RIA for this rule, "Regulatory Impact Analysis: Final Brick and Structural Clay Products NESHAP," which is available in Docket ID No. EPA-HQ-OAR-2013-0291.

<sup>112</sup> U.S. Environmental Protection Agency (U.S. EPA). 2012. *Regulatory Impact Analysis for the Final Revisions to the National Ambient Air Quality Standards for Particulate Matter*. EPA-452/R-12-003. Office of Air Quality Planning and Standards, Health and Environmental Impacts Division. December. Docket Item No. EPA-HQ-OAR-2013-0291-0087.

<sup>109</sup> Krewski, C.A., III, R.T. Burnett, M.J. Thun, E.E. Calle, D. Krewski, K. Ito and G.D. Thurston. 2002. "Lung Cancer, Cardiopulmonary Mortality and Long-term Exposure to Fine Particulate Air Pollution." *Journal of the American Medical Association* 287:1132-1141.

<sup>110</sup> Lepeule J, Laden F, Dockery D, Schwartz J. 2012. "Chronic Exposure to Fine Particles and Mortality: An Extended Follow-Up of the Harvard Six Cities Study from 1974 to 2009." *Environ Health Perspect.* July; 120(7):965-70.

<sup>111</sup> U.S. Environmental Protection Agency (U.S. EPA). 2009. *Integrated Science Assessment for Particulate Matter (Final Report)*. EPA-600-R-08-139F. National Center for Environmental Assessment—RTP Division. December. Available on the Internet at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546>.

## VII. 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 dockets for this action. The EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in "Regulatory Impact Analysis: Final Brick and Structural Clay Products NESHAP." A copy of the analysis is available in the docket for the BSCP Manufacturing NESHAP (Docket ID No. EPA-HQ-OAR-2013-0291) and the analysis is briefly summarized here.

The EPA's study estimates that affected BSCP facilities will incur total annualized costs of \$24.6 million (2011 dollars) under the BSCP Manufacturing NESHAP, including costs of emission controls, testing and monitoring, along with recordkeeping and reporting costs for facilities that have testing and monitoring. The EPA gathered information on firm sales and overall industry profitability for firms owning affected BSCP facilities. The EPA estimated that two to four BSCP manufacturing facilities are at significant risk of closure under the final standards.

The EPA also conducted an assessment of the benefits of the final rule, as described in section VI of this preamble. These estimates reflect the monetized human health benefits of reducing cases of morbidity and premature mortality among populations exposed to PM<sub>2.5</sub> reduced by this rule. Data, resource and methodological limitations prevented the EPA from monetizing the benefits from several important benefit categories, including benefits from reducing exposure to 375 tons of HAP each year for the promulgated standards, as well as ecosystem effects and visibility impairment. In addition to reducing emissions of PM precursors such as SO<sub>2</sub>, this rule will reduce several non-Hg HAP metals emissions (*i.e.*, arsenic, cadmium, chromium, lead, manganese, nickel, and selenium) each year. The EPA estimates the total monetized co-

benefits to be \$83 million to \$190 million (2011 dollars) at a 3-percent discount rate and \$75 million to \$170 million (2011 dollars) at a 7-percent discount rate on a yearly average in 2018 for the promulgated standards.

Based on the EPA's examination of costs and benefits of the final BSCP Manufacturing NESHAP, the EPA believes that the benefits of the BSCP Manufacturing NESHAP will exceed the costs.

The EPA also examined the costs and economic impacts associated with the Clay Ceramics Manufacturing NESHAP. The remaining firm with major sources is estimated to incur costs as a result of the Clay Ceramics Manufacturing final rule and the firm only incurs costs associated with testing, monitoring, recordkeeping and reporting. Total annualized costs are only \$92,400 (2011 dollars) and the firm's estimated costs of complying with the Clay Ceramics Manufacturing NESHAP are less than 0.002 percent of sales.

### B. Paperwork Reduction Act (PRA)

The information collection activities in the BSCP Manufacturing NESHAP and Clay Ceramics Manufacturing NESHAP have been submitted for approval to OMB under the PRA. The ICR document that the EPA prepared for the BSCP Manufacturing NESHAP has been assigned EPA ICR number 2509.01. The ICR document that the EPA prepared for the Clay Ceramics Manufacturing NESHAP has been assigned EPA ICR number 2510.01. You can find copies of the ICRs in the dockets for the BSCP Manufacturing NESHAP and Clay Ceramics Manufacturing NESHAP, and they are briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The information collected from respondents will be used by EPA enforcement personnel to: (1) identify new, modified, reconstructed and existing sources subject to the standards; (2) ensure that MACT is being properly applied; and (3) ensure that the APCD are being properly operated and maintained on a continuous basis. In addition, records and reports are necessary to enable the EPA to identify facilities that may not be in compliance with the standards. Based on the reported information, the EPA can decide which facilities should be inspected and what records or processes should be inspected at these facilities. The records that facilities maintain will indicate to the EPA whether the owners and operators are in compliance with the emission limitations (including

emission limits, operating limits) and work practice standards. Much of the information the EPA would need to determine compliance would be recorded and retained onsite at the facility. Such information would be reviewed by enforcement personnel during an inspection and would not need to be routinely reported to the EPA.

All information submitted to the EPA for which a claim of confidentiality is made will be safeguarded according to EPA policies set forth in title 40, chapter 1, part 2, subpart B—Confidentiality of Business Information. (See 40 CFR 2; 41 FR 36902, September 1, 1976; amended by 43 FR 39999, September 28, 1978; 43 FR 42251, September 28, 1978; and 44 FR 17674, March 23, 1979.)

Potential respondents to the information collection requirements in the BSCP Manufacturing NESHAP are owners and operators of new and existing sources at BSCP manufacturing facilities. A BSCP facility manufactures brick, including face brick, structural brick, brick pavers, or other brick and/or structural clay products including clay pipe; roof tile; extruded floor and wall tile; or other extruded, dimensional clay products. The BSCP facilities typically form, dry and fire bricks and shapes that are composed primarily of clay and shale. Kilns are used to fire BSCP. The rule applies to all new and existing tunnel and periodic kilns at BSCP facilities.

Potential respondents to the information collection requirements in the Clay Ceramics Manufacturing NESHAP are owners and operators of new and existing sources at clay ceramics manufacturing facilities. A clay ceramics facility manufactures pressed floor tile, pressed wall tile, or sanitaryware (*e.g.*, sinks and toilets). Clay ceramics facilities typically form, dry and fire tile or sanitaryware products that are composed of clay, shale and various additives. Spray dryers are used during the forming process at tile facilities to process the ceramic mix into a powder to allow tile pressing. Dryers are used to reduce the moisture content of the ceramic products prior to firing. Glazes are applied to some tile and sanitaryware products, with glaze spraying accounting for all glazing emissions. Kilns are used to fire the ceramic products and include ceramic tile roller kilns and sanitaryware tunnel and shuttle kilns. The rule applies to all existing, new and reconstructed affected sources, which include the kilns, glaze spray operations, ceramic tile spray dryers and floor tile press dryers. (Wall tile press dryers and sanitaryware ware



dryers, with no measurable emissions, are not covered.)

The information requirements are based on notification, recordkeeping and reporting requirements in the NESHAP General Provisions (40 CFR part 63, subpart A), which are mandatory for all operators subject to national emissions standards. These recordkeeping and reporting requirements are specifically authorized by CAA section 114 (42 U.S.C. 7414). All information submitted to the EPA pursuant to the recordkeeping and reporting requirements for which a claim of confidentiality is made is safeguarded according to the EPA policies set forth in 40 CFR part 2, subpart B.

In addition to the notification, recordkeeping and reporting requirements in the NESHAP General Provisions, the final rule includes paperwork requirements associated with initial and 5-year repeat testing for selected process equipment, electronic reporting of performance test results, parameter monitoring, preparation of an OM&M plan, maintenance and inspection of process and control equipment, compliance with work practice standards and periods of malfunction.

Collection of data will begin after the effective date of the final BSCP Manufacturing NESHAP and Clay Ceramics Manufacturing NESHAP. The compliance date for existing sources is 3 years after the effective date. The compliance date for new or reconstructed sources is the effective date if the source startup date is before the effective date, or upon startup if the startup date is on or after the effective date. The schedule for notifications and reports required by the rule is summarized below.

For BSCP and clay ceramics facilities with existing affected sources, the initial notification stating that the facility is subject to the rule must be submitted no later than 120 calendar days after the effective date of the rule. Facilities with new or reconstructed affected sources for which startup occurs on or after the effective date must submit the initial notification no later than 120 calendar days after the source becomes subject to the rule (although we are projecting no new affected sources in the short term). Facilities may choose to submit a request to use the routine control device maintenance alternative standard no later than 120 calendar days prior to the compliance date. Facilities required to conduct a performance test must submit a notification of intent to conduct a performance test at least 60 calendar days before the performance test is

scheduled to begin. For each initial compliance demonstration that includes a performance test, facilities must submit an initial notification of compliance status no later than 60 calendar days following the completion of the performance test. For each initial compliance demonstration that does not involve a performance test, facilities must submit an initial notification within 30 calendar days of completing the initial compliance demonstration. Records necessary to determine compliance with the emission limitations and work practice standards must be compiled on a daily basis, and compliance reports must be submitted to the Administrator on a semiannual basis. Repeat performance tests are to be conducted every 5 years to ensure ongoing compliance.

There are 90 BSCP facilities that are currently major sources of HAP, 84 of which have at least one tunnel kiln. An estimated 21 of these facilities are projected to become synthetic area sources by promulgation rather than comply with the BSCP standards. The remaining 69 facilities (63 of which have a tunnel kiln) are expected to be subject to the BSCP Manufacturing NESHAP. For these 69 facilities, the annual recordkeeping and reporting burden associated with the BSCP standards (averaged over the first 3 years after the effective date of the standards) is estimated to be 20,963 labor hours per year, at a cost of \$1,113,105 per year (yr). Burden is defined at 5 CFR 1320.3(b).

No capital costs associated with monitoring, testing, recordkeeping or reporting are expected to be incurred during this period. The annual operation and maintenance costs are estimated to be \$682/yr.

The total burden for the federal government (averaged over the first 3 years after the effective date of the standards) is estimated to be 71 labor hours per year, at a total labor cost of \$3,698/yr. (All costs are in 2011 dollars.)

There are three clay ceramics facilities that are currently major sources of HAP and are expected to be subject to the Clay Ceramics Manufacturing NESHAP. For these three facilities, the annual recordkeeping and reporting burden associated with the Clay Ceramics standards (averaged over the first 3 years after the effective date of the standards) is estimated to total 996 labor hours per year at a cost of \$52,674/yr.

As with the BSCP standards, no capital costs associated with monitoring, testing, recordkeeping or reporting are expected to be incurred during this period. The annual

operation and maintenance costs are estimated to be \$44/yr.

The total burden for the federal government (averaged over the first 3 years after the effective date of the standards) is estimated to be 4.6 labor hours per year, at a total labor cost of \$239/yr. (All costs are in 2011 dollars.)

Because BSCP and clay ceramics facilities are not required to come into full compliance with the standards until 3 years after promulgation, much of the respondent burden (e.g., performance tests, inspections, notification of compliance status, compliance reports, records of compliance data and malfunctions) does not occur until the fourth year following promulgation.

For the BSCP Manufacturing NESHAP, we estimate an average annual recordkeeping and reporting burden of 48,674 labor hours per year, at a cost of \$2,702,447/yr, for years 4 through 6. We also estimate annualized capital costs of \$606,760/yr and annual operating and maintenance costs of \$206,872/yr over this period, for a total annualized cost of \$813,632/yr. The average annual burden for the federal government for years 4 through 6 is estimated to be 3,891 labor hours per year, at a total labor cost of \$204,550/yr. (All costs are in 2011 dollars.)

For the Clay Ceramics Manufacturing NESHAP, we estimate an average annual recordkeeping and reporting burden of 2,323 labor hours per year, at a cost of \$122,786/yr, for years 4 through 6. We also estimate annualized capital costs of \$72,050/yr and annual operating and maintenance costs of \$27,069/yr over this period, for a total annualized cost of \$99,119/yr. The average annual burden for the federal government for years 4 through 6 is estimated to be 180 labor hours per year, at a total labor cost of \$9,448 per year. (All costs are in 2011 dollars.)

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 the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

### C. Regulatory Flexibility Act (RFA)

Pursuant to sections 603 and 609(b) of the RFA, the EPA prepared an IRFA that examines the impact of the proposed rule on small entities along with regulatory alternatives that could

minimize that impact. The complete IRFA is available for review in the docket and is summarized here. We convened a SBAR Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. Summaries of the IRFA and Panel recommendations are included at 79 FR 75669–75671.

As required by section 604 of the RFA, the EPA prepared a final regulatory flexibility analysis (FRFA) for this action. The FRFA addresses the issues raised by public comments on the IRFA for the proposed rule. The complete FRFA is included in Section 5 of "Regulatory Impact Analysis: Final Brick and Structural Clay Products NESHAP," available for review in the docket (Docket ID No. EPA-HQ-OAR-2013-0291), and is summarized here.

### 1. Need for the Rule

The EPA is required under CAA section 112(d) to establish emission standards for each category or subcategory of major and area sources of HAP listed for regulation in section 112(b). These standards are applicable to new or existing sources of HAP and shall require the maximum degree of emission reduction. In the Administrator's judgment, the pollutants emitted from BSCP manufacturing facilities cause or contribute significantly to air pollution that may reasonably be anticipated to endanger public health. Consequently, NESHAP for the BSCP source category are being finalized.

### 2. Objectives and Legal Basis for the Rule

Section 112(d) of the CAA requires the EPA to set emissions standards for HAP emitted by major stationary sources based on the performance of the MACT. The MACT standards for existing sources must be at least as stringent as the average emissions limitation achieved by the best performing 12 percent of existing sources (for which the Administrator has emissions information) or the best performing five sources for source categories with less than 30 sources (CAA section 112(d)(3)(A) and (B)). For new sources, MACT standards must be at least as stringent as the control level achieved in practice by the best controlled similar source (CAA section 112(d)(3)). The EPA also must consider more stringent "beyond-the-floor" control options. When considering beyond-the-floor options, the EPA must consider not only the maximum degree of reduction in emissions of HAP, but must take into account costs, energy and

non-air environmental impacts when doing so. This rule is being proposed to comply with CAA section 112(d).

### 3. Significant Issues Raised

The EPA received comments on the proposed standards and requests for comment that were included based on SBAR Panel recommendations. See section V of this preamble and "National Emission Standards for Hazardous Air Pollutants for Brick and Structural Clay Products Manufacturing: Background Information for Final Rule—Summary of Public Comments and Responses" in Docket ID No. EPA-HQ-OAR-2013-0291 for more detailed comment summaries and responses.

- *Work practices for dioxin/furan:* One commenter stated that work practices for dioxin/furan emissions from BSCP tunnel kilns are not lawful under the CAA, and, even if they were, the work practices proposed are not sufficient to minimize dioxin/furan emissions. Other commenters supported the proposed work practices for dioxin/furan.

*Response:* The EPA is finalizing work practices for dioxin/furan as proposed. The EPA's response to the legal arguments made against work practice standards is presented in "National Emission Standards for Hazardous Air Pollutants for Brick and Structural Clay Products Manufacturing: Background Information for Final Rule—Summary of Public Comments and Responses" found in the docket (Docket ID No. EPA-HQ-OAR-2013-0291).

- *Work practices for Hg and other metals:* Several commenters responded to the EPA's request for comment on work practices for Hg and non-Hg HAP metals. Numerous commenters stated that the EPA should finalize work practices instead of numeric limits and provided support for their assertion that the numeric limits are technically and economically impracticable to enforce. Commenters also noted that the emissions reduced by these numeric standards are not justified by the high cost that would be incurred to meet the standards.

*Response:* Emissions of Hg and non-Hg HAP metals were detected using standard EPA test methods; therefore, the Hg and non-Hg HAP metals data sets do not meet the criteria for setting work practice standards under CAA section 112(h). The EPA is finalizing numeric standards for Hg and non-Hg HAP metals under CAA section rather than work practices. The final numeric standards have been revised since the proposal to account for new data from the industry (including data on the Hg content of raw materials), removal of

test data found not to meet the requirements of the applicable data, and changes in the EPA's approach to selecting the MACT floor pools (see section V.B.1 of this preamble for additional details).

- *Health-based standard for acid gases:* Several commenters asserted that the EPA may not legally set CAA section 112(d)(4) health-based standards for acid gases for BSCP facilities. Other commenters supported the EPA's decision to propose health-based standards for acid gases but noted that the EPA's approach was overly conservative and requested that the EPA consider setting multiple limits based on site characteristics.

*Response:* The EPA is finalizing the health-based standards for acid gases as proposed. The EPA's response to the legal arguments made against health-based standards is presented in section V.A of this preamble. The EPA is not changing the HBEL from proposal, as the proposed HBEL provides low potential for both chronic and acute health effects.

- *Size subcategories for MACT floors:* Several commenters requested that the EPA subcategorize by size for the non-Hg HAP metal/PM MACT floor limits, as was proposed for Hg.

*Response:* As part of recalculating the MACT floor limits based on the final data set, the EPA is finalizing separate limits for small and large kilns for non-Hg HAP metals/PM as well as Hg. The EPA is also finalizing limits in three different formats for both pollutants to provide additional flexibility for small tunnel kilns and tunnel kilns with a low metals content in the PM emissions.

- *Sawdust dryers:* Several commenters requested that the EPA finalize a subcategory of sawdust-fired kilns venting to sawdust dryers. Commenters provided general descriptions of how the operation of these kilns is different than tunnel kilns and stated that there are only two operating that would be subject to the BSCP Manufacturing NESHAP.

*Response:* Although one commenter noted that stack testing of a sawdust dryer is being considered, commenters did not provide test data to demonstrate that emissions from sawdust dryers are different than other tunnel kilns. Therefore, the EPA is not finalizing a subcategory of sawdust-fired kilns venting to sawdust dryers.

- *Periods of startup and shutdown:* One commenter stated that work practices for periods of startup and shutdown of BSCP tunnel kilns are not lawful under the CAA. Other commenters supported the proposal to provide work practices for periods of

startup and shutdown, but suggested improvements to the standards to make them feasible for all tunnel kilns.

*Response:* The EPA evaluated the comments and is finalizing work practice standards for periods of startup and shutdown that reflect best practices for minimizing emissions during these periods (see section V.B.2 of this preamble for additional information).

- *MACT floor pool:* Several commenters supported the EPA's proposal to calculate MACT floor standards for PM based on the top 12 percent of the kilns in the industry (*i.e.*, the best-performing sources with a FF-based APCD). One commenter asserted that the EPA's proposal is unlawful and the EPA must consider other factors than the APCD type when setting MACT standards.

*Response:* The EPA reviewed all the data used for the MACT floor for PM as a surrogate for non-Hg HAP metals and found that some of the test data did not meet the requirements of EPA Method 5. When these data were removed, the EPA could no longer confirm that the data available to the agency represented all the best-performing sources. Therefore, the final PM and non-Hg HAP metals are based on the top 12 percent of sources for which we had test data, regardless of APCD type (see section V.B.1 of this preamble for additional details).

#### 4. SBA Comments

The SBA's Office of Advocacy supported the EPA's proposals to set work practice standards and health-based emission standards in all instances allowed by statute and suggested other areas of improvement. The comments on areas of improvement and the EPA's responses are summarized below:

- *Hg standards:* The EPA should pursue subcategorization by input (raw material) type and delay promulgation of a Hg standard to gather more information if needed. Standards may need to be combined with a significantly longer averaging time to allow for continuous compliance.

*Response:* The EPA maintains that a delay in promulgation of an Hg standard is not appropriate for two reasons. First, under CAA section 112(e), the EPA was scheduled to complete standards for all source categories by 2000. The EPA's 2003 BSCP Manufacturing NESHAP was vacated, and that vacatur re-created the EPA's obligation to set standards for the BSCP source category. *Sierra Club v. EPA*, 850 F.Supp.2d 300, 303–304 (D.D.C. 2012). Under the consent decree in that case, as amended in August 2014, the EPA was obligated to sign a

notice of final rulemaking to set standards for the BSCP source category by September 24, 2015.

Second, the EPA notes that following proposal, it received additional information on the Hg content of raw materials from facilities in the BSCP industry. This information did not provide the EPA with the information needed to establish subcategories based on the class or type of raw materials. However, the EPA has concluded that it has sufficient information to allow it to finalize Hg standards that account for the variability of Hg content in raw materials. Thus, the EPA's conclusion is that there is no basis to delay promulgation of the Hg standards in order to gather more information.

- *Economic analysis:* The economic impact of the proposed rule on small entities is significantly underestimated. Specifically, the EPA should not annualize costs at 7 percent over 20 years because that does not reflect the financing options available to small entities, the EPA underestimated the cost for a facility to become a synthetic area source, and the EPA has underestimated the cost to comply with the Hg standards given the limited information the agency has on the performance of Hg controls in this industry.

*Response:* The EPA standard engineering cost practice is to annualize over the expected life of the control equipment at 7 percent. The EPA does not have the data available to model the way a firm pays for an APCD because each firm has a different set of potential options for financing including debt financing, equity financing, and financing through retained earnings. The EPA acknowledges that some firms may not be able to borrow the money and some may close. The EPA's closure analysis is quite uncertain, but we do not have the detailed firm-specific information necessary to refine the analysis. The EPA agrees that the costs to become a synthetic area source at proposal were underestimated, and the final rule impacts include testing costs for all facilities, as potential synthetic area sources would have to demonstrate that their emissions qualify them to apply for synthetic area status. Finally, the EPA must use the best information available to the agency to estimate the impact of the standards on all entities. The final Hg standards incorporate variability in the Hg content of raw materials, which is expected to ease the burdens on some small entities.

#### 5. Affected Small Entities

Of 44 parent companies owning BSCP facilities, 36 parent companies are small

businesses. The EPA computed the ratio of estimated compliance costs to company sales (cost-to-sales ratio) to measure the magnitude of potential impacts on small companies. Under the final standards, the EPA estimated that two to three small BSCP manufacturing facilities (two to four BSCP manufacturing facilities overall) are at significant risk of closure.

#### 6. Reporting, Recordkeeping, and Other Compliance Requirements

Respondents would be required to provide one-time and periodic notifications, including initial notification, notification of performance tests, and notification of compliance status. Respondents would also be required to submit semiannual reports documenting compliance with the rule and detailing any compliance issues, and they would be required to submit the results of performance tests to the EPA's ERT. Respondents would be required to keep documentation supporting information included in these notifications and reports, as well as records of the operation and maintenance of affected sources and APCD at the facility.

#### 7. Significant Alternatives

The EPA considered three major options for this final rule; see "Regulatory Impact Analysis: Final Brick and Structural Clay Products NESHAP," in Docket ID No. EPA-HQ-OAR-2013-0291, for more information about the alternatives. Finalizing the proposed changes without revision is expected to have similar cost and emission reduction impacts to the standards the EPA is finalizing, with a similar number of closures (one to two small BSCP manufacturing facilities rather than two to three). However, for the various legal and technical reasons outlined in this preamble and "National Emission Standards for Hazardous Air Pollutants for Brick and Structural Clay Products Manufacturing: Background Information for Final Rule—Summary of Public Comments and Responses" in Docket ID No. EPA-HQ-OAR-2013-0291, the EPA determined that the PM/non-Hg HAP metals and Hg standards should not be finalized as proposed. The other alternative considered included the same standards for acid gases and Hg that are being finalized but only provided one set of limits PM/non-Hg HAP metals (*i.e.*, did not provide separate sets of limits for small and large tunnel kilns). This alternative is expected to have significantly higher cost impacts than the standards the EPA is finalizing, along with a significantly higher number of closures (five to 10

small BSCP manufacturing facilities rather than two to three small BSCP manufacturing facilities). Therefore, the EPA determined that it is necessary to exercise its discretion to subcategorize by kiln size to minimize the significant economic impact on small entities.

In addition, the EPA is preparing a Small Entity Compliance Guide to help small entities comply with this rule. The guide will be available on the World Wide Web approximately 1 year after promulgation of the rule, at <http://www.epa.gov/ttn/atw/brick/brickpg.html>.

#### *D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of \$100 million or more as described in the UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

#### *E. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175. The action imposes requirements on owners and operators of BSCP and clay ceramics manufacturing facilities and not tribal governments. Thus, Executive Order 13175 does not apply to this action.

#### *G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in the memoranda "Risk Assessment to Determine a Health-Based Emission

Limitation for Acid Gases for the Brick and Structural Clay Products Manufacturing Source Category," Docket Item No. EPA-HQ-OAR-2013-0291-0132 and "Risk Assessment to Determine a Health-Based Emission Limitation for Acid Gases for the Clay Ceramics Manufacturing Source Category," Docket Item No. EPA-HQ-OAR-2013-0290-0213.

#### *H. Executive Order 13211: Actions Concerning Regulations 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. This action will not adversely directly affect productivity, competition, or prices in the energy sector.

#### *I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51*

This action involves technical standards. The EPA has decided to use the following four voluntary consensus standards as acceptable alternatives to the EPA test methods for the purpose of this rule.

The EPA has decided to use ANSI/ASME PTC 19.10-1981, "Flue and Exhaust Gas Analyses," for its manual methods of measuring the oxygen or carbon dioxide content of the exhaust gas. This standard is acceptable as an alternative to Method 3A and 3B and is available from the American Society of Mechanical Engineers (ASME) at <http://www.asme.org>; by mail at Three Park Avenue, New York, NY 10016-5990; or by telephone at (800) 843-2763.

The EPA has also decided to use ASTM D6735-01 (Reapproved 2009), "Standard Test Method for Measurement of Gaseous Chlorides and Fluorides from Mineral Calcining Exhaust Sources—Impinger Method," for its measurement of the concentration of gaseous HCl and HF and other gaseous chlorides and fluorides. This standard is acceptable as an alternative to Methods 26 and 26A.

In addition, the EPA has decided to use ASTM D6784-02 (Reapproved 2008), "Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method)," for its determination of elemental, oxidized, particle-bound, and total Hg emissions. This standard is acceptable as an alternative to Method 29 (portion for Hg only).

Finally, the EPA has decided to use ASTM D6348-03 (Reapproved 2010), "Standard Test Method for

Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy," for its use of an extractive sampling system to direct stationary source effluent to an FTIR spectrometer for the identification and quantification of gaseous compounds. This standard is acceptable as an alternative to Method 320 with the following conditions: (1) The test plan preparation and implementation in the Annexes to ASTM D 6348-03, Sections A1 through A8 are mandatory; and (2) in ASTM D6348-03 Annex A5 (Analyte Spiking Technique), the percent recovery (%R) must be determined for each target analyte (Equation A5.5). In order for the test data to be acceptable for a compound, %R must be greater than or equal to 70 percent and less than or equal to 130 percent. If the %R value does not meet this criterion for a target compound, the test data are not acceptable for that compound and the test must be repeated for that analyte (*i.e.*, the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report and all field measurements must be corrected with the calculated %R value for that compound by using the following equation: Reported Result = (Measured Concentration in the Stack × 100)/%R.

The standards ASTM D6735-01, ASTM D6784-02, and ASTM D6348-03 are available from the American Society of Testing and Materials (ASTM) at <http://www.astm.org>; by mail at 100 Barr Harbor Drive, Post Office Box C700, West Conshohocken, PA 19428-2959; or by telephone at (610) 832-9585.

While the EPA identified ASTM D7520-13, "Standard Test Method for Determining the Opacity in a Plume in an Outdoor Ambient Atmosphere" as being potentially applicable as an alternative to Method 9 for measuring opacity from BSCP tunnel kilns, the agency decided not to use it. The use of this voluntary consensus standard would be impractical. The five provisions for the use of this standard appear to be based on the assumption that the optical camera will be used on a daily basis. However, this rulemaking does not include daily Method 9 tests. The rule requirements are such that a Method 9 observation would need to be made unexpectedly and only when the Method 22 test failed. It would be unreasonable to expect that a source would be making daily calibrations of the camera when its use would be so infrequent. Given that, it is unlikely that the camera could be made ready in the time specified for the Method 9

readings. Therefore, this standard is not usable based on the current requirements in this rulemaking.

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. As explained in the December 2014 proposal (79 FR 75672), the EPA determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations, because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. Additionally, the agency has conducted a proximity analysis for this rulemaking, which is located in the docket. (See "EJ Screening Report for Brick and Structural Clay," Docket Item No. EPA-HQ-OAR-2013-0291-0102, and "EJ Screening Report for Clay Ceramics," Docket Item No. EPA-HQ-OAR-2013-0290-0241.)

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each house of the Congress and to the Comptroller General of the United States. This action is a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: September 24, 2015.

Gina McCarthy, Administrator.

For the reasons discussed in the preamble, the Environmental Protection Agency amends 40 CFR part 63 as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

- 2. Section 63.14 is amended by:
■ a. Revising paragraph (g)(1);
■ b. Revising paragraph (h)(75);
■ c. Redesignating paragraphs (h)(86) through (98) as paragraphs (h)(87) through (99), respectively;
■ d. Adding new paragraph (h)(86);
■ e. Revising newly redesignated paragraph (h)(88); and
■ f. Revising paragraph (m)(2).

The revisions and additions read as follows:

§ 63.14 Incorporations by reference.

(g) \* \* \*
(1) ANSI/ASME PTC 19.10-1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981, IBR approved for §§ 63.309(k), 63.457(k), 63.772(e) and (h), 63.865(b), 63.1282(d) and (g), 63.1625(b), 63.3166(a), 63.3360(e), 63.3545(a), 63.3555(a), 63.4166(a), 63.4362(a), 63.4766(a), 63.4965(a), 63.5160(d), table 4 to subpart UUUU, 63.9307(c), 63.9323(a), 63.11148(e), 63.11155(e), 63.11162(f), 63.11163(g), 63.11410(j), 63.11551(a), 63.11646(a), and 63.11945, table 5 to subpart DDDDD, table 4 to subpart JJJJJ, table 4 to subpart KKKKK, tables 4 and 5 of subpart UUUUU, table 1 to subpart ZZZZZ, and table 4 to subpart JJJJJJ.

(h) \* \* \*

(75) ASTM D6348-03 (Reapproved 2010), Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, including Annexes A1 through A8, (Approved October 1, 2010), IBR approved for tables 4 and 5 to subpart JJJJJ, tables 4 and 6 to subpart KKKKK, tables 1, 2, and 5 to subpart UUUUU, and appendix B to subpart UUUUU.

(86) ASTM D6735-01 (Reapproved 2009), Standard Test Method for Measurement of Gaseous Chlorides and Fluorides from Mineral Calcining Exhaust Sources—Impinger Method, IBR approved for tables 4 and 5 to subpart JJJJJ and tables 4 and 6 to subpart KKKKK.

(88) ASTM D6784-02 (Reapproved 2008), Standard Test Method for

Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method), (Approved April 1, 2008), IBR approved for §§ 63.11646(a), 63.11647(a) and (d), tables 1, 2, 5, 11, 12t, and 13 to subpart DDDDD, tables 4 and 5 to subpart JJJJJ, tables 4 and 6 to subpart KKKKK, table 4 to subpart JJJJJJ, table 5 to subpart UUUUU, and appendix A to subpart UUUUU.

(m) \* \* \*

(2) EPA-454/R-98-015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997, IBR approved for §§ 63.548(e), 63.7525(j), 63.8450(e), 63.8600(e), and 63.11224(f).

■ 3. Part 63 is amended by revising subpart JJJJJ to read as follows:

Subpart JJJJJ—National Emission Standards for Hazardous Air Pollutants for Brick and Structural Clay Products Manufacturing

Sec.

What This Subpart Covers

- 63.8380 What is the purpose of this subpart?
63.8385 Am I subject to this subpart?
63.8390 What parts of my plant does this subpart cover?
63.8395 When do I have to comply with this subpart?

Emission Limitations and Work Practice Standards

- 63.8405 What emission limitations and work practice standards must I meet?
63.8410 What are my options for meeting the emission limitations and work practice standards?

General Compliance Requirements

- 63.8420 What are my general requirements for complying with this subpart?
63.8425 What do I need to know about operation, maintenance, and monitoring plans?

Testing and Initial Compliance Requirements

- 63.8435 By what date must I conduct performance tests?
63.8440 When must I conduct subsequent performance tests?
63.8445 How do I conduct performance tests and establish operating limits?
63.8450 What are my monitoring installation, operation, and maintenance requirements?
63.8455 How do I demonstrate initial compliance with the emission limitations and work practice standards?

**Continuous Compliance Requirements**

- 63.8465 How do I monitor and collect data to demonstrate continuous compliance?
- 63.8470 How do I demonstrate continuous compliance with the emission limitations and work practice standards?

**Notifications, Reports, and Records**

- 63.8480 What notifications must I submit and when?
- 63.8485 What reports must I submit and when?
- 63.8490 What records must I keep?
- 63.8495 In what form and for how long must I keep my records?

**Other Requirements and Information**

- 63.8505 What parts of the General Provisions apply to me?
- 63.8510 Who implements and enforces this subpart?
- 63.8515 What definitions apply to this subpart?

**Tables to Subpart JJJJJ of Part 63**

- Table 1 to Subpart JJJJJ of Part 63—Emission Limits
- Table 2 to Subpart JJJJJ of Part 63—Operating Limits
- Table 3 to Subpart JJJJJ of Part 63—Work Practice Standards
- Table 4 to Subpart JJJJJ of Part 63—Requirements for Performance Tests
- Table 5 to Subpart JJJJJ of Part 63—Initial Compliance with Emission Limitations and Work Practice Standards
- Table 6 to Subpart JJJJJ of Part 63—Continuous Compliance with Emission Limitations and Work Practice Standards
- Table 7 to Subpart JJJJJ of Part 63—Compliance Dates
- Table 8 to Subpart JJJJJ of Part 63—Requirements for Notifications
- Table 9 to Subpart JJJJJ of Part 63—Requirements for Reports
- Table 10 to Subpart JJJJJ of Part 63—Applicability of General Provisions to Subpart JJJJJ

**Subpart JJJJJ—National Emission Standards for Hazardous Air Pollutants for Brick and Structural Clay Products Manufacturing****What This Subpart Covers****§ 63.8380 What is the purpose of this subpart?**

This subpart establishes national emission limitations for hazardous air pollutants (HAP) emitted from brick and structural clay products (BSCP) manufacturing facilities. This subpart also establishes requirements to demonstrate initial and continuous compliance with the emission limitations.

**§ 63.8385 Am I subject to this subpart?**

You are subject to this subpart if you own or operate a BSCP manufacturing facility that is, is located at, or is part of, a major source of HAP emissions

according to the criteria in paragraphs (a) and (b) of this section.

(a) A BSCP manufacturing facility is a plant site that manufactures brick (including, but not limited to, face brick, structural brick, and brick pavers); clay pipe; roof tile; extruded floor and wall tile; and/or other extruded, dimensional clay products. Brick and structural clay products manufacturing facilities typically process raw clay and shale, form the processed materials into bricks or shapes, and dry and fire the bricks or shapes. A plant site that manufactures refractory products, as defined in § 63.9824, or clay ceramics, as defined in § 63.8665, is not a BSCP manufacturing facility.

(b) A major source of HAP emissions is any stationary source or group of stationary sources within a contiguous area under common control that emits or has the potential to emit any single HAP at a rate of 9.07 megagrams (10 tons) or more per year or any combination of HAP at a rate of 22.68 megagrams (25 tons) or more per year.

**§ 63.8390 What parts of my plant does this subpart cover?**

(a) This subpart applies to each existing, new, or reconstructed affected source at a BSCP manufacturing facility.

(b) For the purposes of this subpart, the affected sources are described in paragraphs (b)(1) and (2) of this section.

(1) All tunnel kilns at a BSCP manufacturing facility are an affected source. For the remainder of this subpart, a tunnel kiln with a design capacity equal to or greater than 9.07 megagrams per hour (Mg/hr) (10 tons per hour (tph)) of fired product will be called a large tunnel kiln, and a tunnel kiln with a design capacity less than 9.07 Mg/hr (10 tph) of fired product will be called a small tunnel kiln.

(2) Each periodic kiln is an affected source.

(c) Process units not subject to the requirements of this subpart are listed in paragraphs (c)(1) through (4) of this section.

(1) Kilns that are used exclusively for setting glazes on previously fired products are not subject to the requirements of this subpart.

(2) Raw material processing and handling.

(3) Dryers.

(4) Sources covered by subparts KKKKK and SSSSS of this part.

(d) A source is a new affected source if construction of the affected source began after December 18, 2014, and you met the applicability criteria at the time you began construction.

(e) An affected source is reconstructed if you meet the criteria as defined in § 63.2.

(f) An affected source is existing if it is not new or reconstructed.

**§ 63.8395 When do I have to comply with this subpart?**

(a) You must comply with this subpart no later than the compliance dates in Table 7 to this subpart.

(b) You must meet the notification requirements in § 63.8480 according to the schedule in § 63.8480 and in subpart A of this part. Some of the notifications must be submitted before you are required to comply with the emission limitations in this subpart.

**Emission Limitations and Work Practice Standards****§ 63.8405 What emission limitations and work practice standards must I meet?**

(a) You must meet each emission limit in Table 1 to this subpart that applies to you.

(b) You must meet each operating limit in Table 2 to this subpart that applies to you.

(c) You must meet each work practice standard in Table 3 to this subpart that applies to you.

**§ 63.8410 What are my options for meeting the emission limitations and work practice standards?**

(a) To meet the emission limitations in Tables 1 and 2 to this subpart, you must use one or more of the options listed in paragraphs (a)(1) and (2) of this section.

(1) *Emissions control system.* Use an emissions capture and collection system and an air pollution control device (APCD) and demonstrate that the resulting emissions meet the emission limits in Table 1 to this subpart, and that the capture and collection system and APCD meet the applicable operating limits in Table 2 to this subpart.

(2) *Process changes.* Use low-HAP raw materials or implement manufacturing process changes and demonstrate that the resulting emissions or emissions reductions meet the emission limits in Table 1 to this subpart.

(b) To meet the work practice standards for affected periodic kilns, you must comply with the requirements listed in Table 3 to this subpart.

(c) To meet the work practice standards for dioxins/furans for affected tunnel kilns, you must comply with the requirements listed in Table 3 to this subpart.

(d) To meet the work practice standards for affected tunnel kilns during periods of startup and shutdown, you must comply with the requirements listed in Table 3 to this subpart.

## General Compliance Requirements

### § 63.8420 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the emission limitations (including operating limits) in this subpart at all times, except during periods that you are approved for and in compliance with the alternative standard for routine control device maintenance as specified in paragraph (d) of this section, and except during periods of start-up and shutdown, at which time you must comply with the applicable work practice standard specified in Table 3 to this subpart.

(b) At all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source. During the period between the compliance date specified for your affected source in § 63.8395 and the date upon which continuous monitoring systems (CMS) (e.g., continuous parameter monitoring systems) have been installed and verified and any applicable operating limits have been set, you must maintain a log detailing the operation and maintenance of the process and emissions control equipment.

(c) For each affected kiln that is subject to the emission limits specified in Table 1 to this subpart, you must prepare and implement a written operation, maintenance, and monitoring (OM&M) plan according to the requirements in § 63.8425.

(d) If you own or operate an affected kiln that is subject to the emission limits specified in Table 1 to this subpart and must perform routine maintenance on the control device for that kiln, you may bypass the kiln control device and continue operating the kiln subject to the alternative standard established in this paragraph upon approval by the Administrator and provided you satisfy

the conditions listed in paragraphs (d)(1) through (5) of this section.

(1) You must request to use the routine control device maintenance alternative standard from the Administrator no later than 120 calendar days before the compliance date specified in § 63.8395. Your request must justify the need for the routine maintenance on the control device and the time required to accomplish the maintenance activities, describe the maintenance activities and the frequency of the maintenance activities, explain why the maintenance cannot be accomplished during kiln shutdowns, provide information stating whether the continued operation of the affected source will result in fewer emissions than shutting the source down while the maintenance is performed, describe how you plan to comply with paragraph (b) of this section during the maintenance, and provide any other documentation required by the Administrator.

(2) The routine control device maintenance must not exceed 4 percent of the annual operating uptime for each kiln.

(3) The request for the routine control device maintenance alternative standard, if approved by the Administrator, must be incorporated by reference in and attached to the affected source's title V permit.

(4) You must minimize HAP emissions during the period when the kiln is operating and the control device is offline by complying with the applicable standard in Table 3 to this subpart.

(5) You must minimize the time period during which the kiln is operating and the control device is offline.

(e) You must be in compliance with the work practice standards in this subpart at all times.

(f) You must be in compliance with the provisions of subpart A of this part, except as noted in Table 10 to this subpart.

### § 63.8425 What do I need to know about operation, maintenance, and monitoring plans?

(a) For each affected kiln that is subject to the emission limits specified in Table 1 to this subpart, you must prepare, implement, and revise as necessary an OM&M plan that includes the information in paragraph (b) of this section. Your OM&M plan must be available for inspection by the delegated authority upon request.

(b) Your OM&M plan must include, as a minimum, the information in paragraphs (b)(1) through (13) of this section.

(1) Each process and APCD to be monitored, the type of monitoring device that will be used, and the operating parameters that will be monitored.

(2) A monitoring schedule that specifies the frequency that the parameter values will be determined and recorded.

(3) The limits for each parameter that represent continuous compliance with the emission limitations in § 63.8405. The limits must be based on values of the monitored parameters recorded during performance tests.

(4) Procedures for the proper operation and routine and long-term maintenance of each APCD, including a maintenance and inspection schedule that is consistent with the manufacturer's recommendations.

(5) Procedures for installing the CMS sampling probe or other interface at a measurement location relative to each affected process unit such that the measurement is representative of control of the exhaust emissions (e.g., on or downstream of the last APCD).

(6) Performance and equipment specifications for the sample interface, the pollutant concentration or parametric signal analyzer, and the data collection and reduction system.

(7) Continuous monitoring system performance evaluation procedures and acceptance criteria (e.g., calibrations).

(8) Procedures for the proper operation and maintenance of monitoring equipment consistent with the requirements in §§ 63.8450 and 63.8(c)(1), (3), (7), and (8).

(9) Continuous monitoring system data quality assurance procedures consistent with the requirements in § 63.8(d)(1) and (2). The owner or operator shall keep these written procedures on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan in § 63.8(d)(2) is revised, the owner or operator shall keep previous (i.e., superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2).

(10) Continuous monitoring system recordkeeping and reporting procedures consistent with the requirements in §§ 63.8485 and 63.8490.

(11) Procedures for responding to operating parameter deviations,



including the procedures in paragraphs (b)(11)(i) through (iii) of this section.

(i) Procedures for determining the cause of the operating parameter deviation.

(ii) Actions necessary for correcting the deviation and returning the operating parameters to the allowable limits.

(iii) Procedures for recording the times that the deviation began and ended and corrective actions were initiated and completed.

(12) Procedures for keeping records to document compliance.

(13) If you operate an affected kiln and you plan to take the kiln control device out of service for routine maintenance, as specified in § 63.8420(d), the procedures specified in paragraphs (b)(13)(i) and (ii) of this section.

(i) Procedures for minimizing HAP emissions from the kiln during periods of routine maintenance of the kiln control device when the kiln is operating and the control device is offline.

(ii) Procedures for minimizing the duration of any period of routine maintenance on the kiln control device when the kiln is operating and the control device is offline.

(c) Changes to the operating limits in your OM&M plan require a new performance test. If you are revising an operating limit parameter value, you must meet the requirements in paragraphs (c)(1) and (2) of this section.

(1) Submit a notification of performance test to the Administrator as specified in § 63.7(b).

(2) After completing the performance tests to demonstrate that compliance with the emission limits can be

achieved at the revised operating limit parameter value, you must submit the performance test results and the revised operating limits as part of the Notification of Compliance Status required under § 63.9(h).

(d) If you are revising the inspection and maintenance procedures in your OM&M plan, you do not need to conduct a new performance test.

#### Testing and Initial Compliance Requirements

##### § 63.8435 By what date must I conduct performance tests?

For each affected kiln that is subject to the emission limits specified in Table 1 to this subpart, you must conduct performance tests within 180 calendar days after the compliance date that is specified for your source in § 63.8395 and according to the provisions in § 63.7(a)(2).

##### § 63.8440 When must I conduct subsequent performance tests?

(a) For each affected kiln that is subject to the emission limits specified in Table 1 to this subpart, you must conduct a performance test before renewing your 40 CFR part 70 operating permit or at least every 5 years following the initial performance test.

(b) You must conduct a performance test when you want to change the parameter value for any operating limit specified in your OM&M plan.

##### § 63.8445 How do I conduct performance tests and establish operating limits?

(a) You must conduct each performance test in Table 4 to this subpart that applies to you.

(b) Before conducting the performance test, you must install and calibrate all monitoring equipment.

(c) Each performance test must be conducted according to the requirements in § 63.7 and under the specific conditions in Table 4 to this subpart.

(d) Performance tests shall be conducted under such conditions as the Administrator specifies to you based on representative performance of the affected source for the period being tested. Representative conditions exclude periods of startup and shutdown. You may not conduct performance tests during periods of malfunction. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(e) You must conduct at least three separate test runs for each performance test required in this section, as specified in § 63.7(e)(3). Each test run must last at least 1 hour.

(f) You must use the data gathered during the performance test and the equations in paragraphs (f)(1) and (2) of this section to determine compliance with the emission limitations.

(1) To determine compliance with the production-based particulate matter (PM) and mercury (Hg) emission limits in Table 1 to this subpart, you must calculate your mass emissions per unit of production for each test run using Equation 1:

$$MP = \frac{ER}{P} \quad (\text{Eq. 1})$$

Where:

MP = mass per unit of production, kilograms (pounds) of pollutant per megagram (ton) of fired product

ER = mass emission rate of pollutant (PM or Hg) during each performance test run, kilograms (pounds) per hour

P = production rate during each performance test run, megagrams (tons) of fired product per hour.

(2) To determine compliance with the health-based standard for acid gas HAP

for BSCP manufacturing facilities in Table 1 to this subpart, you must:

(i) Calculate the HCl-equivalent emissions for HF, HCl, and Cl<sub>2</sub> for each tunnel kiln at your facility using Equation 2:

$$E_i = E_{HCl} + \left[ E_{HF} \left( \frac{RfC_{HCl}}{RfC_{HF}} \right) \right] + \left[ E_{Cl_2} \left( \frac{RfC_{HCl}}{RfC_{Cl_2}} \right) \right] \quad (\text{Eq. 2})$$

Where:

E<sub>i</sub> = HCl-equivalent emissions for kiln i, kilograms (pounds) per hour

E<sub>HCl</sub> = emissions of HCl, kilograms (pounds) per hour

E<sub>HF</sub> = emissions of HF, kilograms (pounds) per hour

E<sub>Cl<sub>2</sub></sub> = emissions of Cl<sub>2</sub>, kilograms (pounds) per hour

RfC<sub>HCl</sub> = reference concentration for HCl, 20 micrograms per cubic meter

RfC<sub>HF</sub> = reference concentration for HF, 14 micrograms per cubic meter  
 RfC<sub>Cl<sub>2</sub></sub> = reference concentration for Cl<sub>2</sub>, 0.15 micrograms per cubic meter

(ii) If you have multiple tunnel kilns at your facility, sum the HCl-equivalent

values for all tunnel kilns at the facility using Equation 3:

$$E_{total} = \sum_{i=1}^n E_i \quad (\text{Eq. 3})$$

Where:

E<sub>total</sub> = HCl-equivalent emissions for total of all kilns at facility, kilograms (pounds) per hour

E<sub>i</sub> = HCl-equivalent emissions for kiln i, kilograms (pounds) per hour

n = number of tunnel kilns at facility

(iii) Compare this value to the health-based standard in Table 1 to this subpart.

(g) You must establish each site-specific operating limit in Table 2 to this subpart that applies to you as specified in paragraph (g)(1) of this section and in Table 4 to this subpart.

(1)(i) If you do not have an APCD installed on your kiln, calculate the maximum potential HCl-equivalent emissions for HF, HCl, and Cl<sub>2</sub> for each tunnel kiln at your facility using Equation 4:

$$E_{max\ i} = (Cap_i) \left[ (MP_{iHCl}) + (MP_{iHF}) \left( \frac{RfC_{HCl}}{RfC_{HF}} \right) + (MP_{iCl_2}) \left( \frac{RfC_{HCl}}{RfC_{Cl_2}} \right) \right] \quad (\text{Eq. 4})$$

Where:

E<sub>max i</sub> = maximum potential HCl-equivalent emissions for kiln i, kilograms (pounds) per hour

Cap<sub>i</sub> = design capacity for kiln i, megagrams (tons) of fired product per hour

MP<sub>iHCl</sub> = mass of HCl per unit of production for kiln i, kilograms (pounds) of HCl per megagram (ton) of fired product

MP<sub>iHF</sub> = mass of HF per unit of production for kiln i, kilograms (pounds) of HF per megagram (ton) of fired product

MP<sub>iCl<sub>2</sub></sub> = mass of Cl<sub>2</sub> per unit of production for kiln i, kilograms (pounds) of Cl<sub>2</sub> per megagram (ton) of fired product

RfC<sub>HCl</sub> = reference concentration for HCl, 20 micrograms per cubic meter

RfC<sub>HF</sub> = reference concentration for HF, 14 micrograms per cubic meter

RfC<sub>Cl<sub>2</sub></sub> = reference concentration for Cl<sub>2</sub>, 0.15 micrograms per cubic meter

(ii) If you have multiple tunnel kilns at your facility, sum the maximum potential HCl-equivalent values for all tunnel kilns at the facility using Equation 5:

$$E_{max\ total} = \sum_{i=1}^n E_{max\ i} \quad (\text{Eq. 5})$$

Where:

E<sub>max total</sub> = maximum potential HCl-equivalent emissions for total of all kilns at facility, kilograms (pounds) per hour

E<sub>max i</sub> = maximum potential HCl-equivalent emissions for kiln i, kilograms (pounds) per hour

n = number of tunnel kilns at facility

(iii) If you have a single tunnel kiln at your facility and the total facility maximum potential HCl-equivalent emissions (E<sub>max total</sub>) are greater than the HCl-equivalent limit in Table 1 to this subpart, determine the maximum process rate for the tunnel kiln using

Equation 6 that would ensure the total facility maximum potential HCl-equivalent emissions remain at or below the HCl-equivalent limit. The maximum process rate would become your operating limit for process rate and must be included in your OM&M plan.

$$P_{max\ i} = \frac{HCl - eq}{\left[ (MP_{iHCl}) + (MP_{iHF}) \left( \frac{RfC_{HCl}}{RfC_{HF}} \right) + (MP_{iCl_2}) \left( \frac{RfC_{HCl}}{RfC_{Cl_2}} \right) \right]} \quad (\text{Eq. 6})$$

Where:

P<sub>max i</sub> = maximum process rate for kiln i, megagrams (tons) per hour

HCl-eq = HCl-equivalent limit in Table 1 to this subpart, 26 kilograms (57 pounds) per hour

MP<sub>iHCl</sub> = mass of HCl per unit of production for kiln i, kilograms (pounds) of HCl per megagram (ton) of fired product

MP<sub>iHF</sub> = mass of HF per unit of production for kiln i, kilograms (pounds) of HF per megagram (ton) of fired product

MP<sub>iCl<sub>2</sub></sub> = mass of Cl<sub>2</sub> per unit of production for kiln i, kilograms (pounds) of Cl<sub>2</sub> per megagram (ton) of fired product

RfC<sub>HCl</sub> = reference concentration for HCl, 20 micrograms per cubic meter

RfC<sub>HF</sub> = reference concentration for HF, 14 micrograms per cubic meter

RfC<sub>Cl<sub>2</sub></sub> = reference concentration for Cl<sub>2</sub>, 0.15 micrograms per cubic meter

(iv) If you have multiple tunnel kilns at your facility and the total facility maximum potential HCl-equivalent

emissions (E<sub>max total</sub>) are greater than the HCl-equivalent limit in Table 1 to this subpart, determine the combination of maximum process rates that would ensure that total facility maximum potential HCl-equivalent remains at or below the HCl-equivalent limit. The maximum process rates would become your operating limits for process rate and must be included in your OM&M plan.

(2) [Reserved]

(h) For each affected kiln that is subject to the emission limits specified in Table 1 to this subpart and is equipped with an APCD that is not addressed in Table 2 to this subpart or that is using process changes as a means of meeting the emission limits in Table 1 to this subpart, you must meet the requirements in § 63.8(f) and paragraphs (h)(1) and (2) of this section.

(1) Submit a request for approval of alternative monitoring procedures to the Administrator no later than the notification of intent to conduct a performance test. The request must contain the information specified in paragraphs (h)(1)(i) through (iv) of this section.

(i) A description of the alternative APCD or process changes.

(ii) The type of monitoring device or procedure that will be used.

(iii) The operating parameters that will be monitored.

(iv) The frequency that the operating parameter values will be determined and recorded to establish continuous compliance with the operating limits.

(2) Establish site-specific operating limits during the performance test based on the information included in the approved alternative monitoring procedures request and, as applicable, as specified in Table 4 to this subpart.

**§ 63.8450 What are my monitoring installation, operation, and maintenance requirements?**

(a) You must install, operate, and maintain each CMS according to your OM&M plan and the requirements in paragraphs (a)(1) through (5) of this section.

(1) Conduct a performance evaluation of each CMS according to your OM&M plan.

(2) The CMS must complete a minimum of one cycle of operation for each successive 15-minute period. To have a valid hour of data, you must have at least three of four equally spaced data values (or at least 75 percent if you collect more than four data values per hour) for that hour (not including startup, shutdown, malfunction, out-of-control periods, or periods of routine control device maintenance covered by the routine control device maintenance alternative standard as specified in § 63.8420(d)).

(3) Determine and record the 3-hour block averages of all recorded readings, calculated after every 3 hours of operation as the average of the previous 3 operating hours. To calculate the average for each 3-hour average period, you must have at least 75 percent of the recorded readings for that period (not

including startup, shutdown, malfunction, out-of-control periods, or periods of routine control device maintenance covered by the routine control device maintenance alternative standard as specified in § 63.8420(d)).

(4) Record the results of each inspection, calibration, and validation check.

(5) At all times, maintain the monitoring equipment including, but not limited to, maintaining necessary parts for routine repairs of the monitoring equipment.

(b) For each liquid flow measurement device, you must meet the requirements in paragraphs (a)(1) through (5) and paragraphs (b)(1) through (3) of this section.

(1) Locate the flow sensor in a position that provides a representative flowrate.

(2) Use a flow sensor with a minimum measurement sensitivity of 2 percent of the liquid flowrate.

(3) At least semiannually, conduct a flow sensor calibration check.

(c) For each pressure measurement device, you must meet the requirements in paragraphs (a)(1) through (5) and paragraphs (c)(1) through (7) of this section.

(1) Locate the pressure sensor(s) in or as close to a position that provides a representative measurement of the pressure.

(2) Minimize or eliminate pulsating pressure, vibration, and internal and external corrosion.

(3) Use a gauge with a minimum measurement sensitivity of 0.5 inch of water or a transducer with a minimum measurement sensitivity of 1 percent of the pressure range.

(4) Check the pressure tap daily to ensure that it is not plugged.

(5) Using a manometer, check gauge calibration quarterly and transducer calibration monthly.

(6) Any time the sensor exceeds the manufacturer's specified maximum operating pressure range, conduct calibration checks or install a new pressure sensor.

(7) At least monthly, inspect all components for integrity, all electrical connections for continuity, and all mechanical connections for leakage.

(d) For each pH measurement device, you must meet the requirements in paragraphs (a)(1) through (5) and paragraphs (d)(1) through (4) of this section.

(1) Locate the pH sensor in a position that provides a representative measurement of pH.

(2) Ensure the sample is properly mixed and representative of the fluid to be measured.

(3) Check the pH meter's calibration at one point daily.

(4) At least monthly, inspect all components for integrity and all electrical connections for continuity.

(e) For each bag leak detection system, you must meet the requirements in paragraphs (e)(1) through (11) of this section.

(1) Each triboelectric bag leak detection system must be installed, calibrated, operated, and maintained according to EPA-454/R-98-015, "Fabric Filter Bag Leak Detection Guidance," (incorporated by reference, see § 63.14). Other types of bag leak detection systems must be installed, operated, calibrated, and maintained in a manner consistent with the manufacturer's written specifications and recommendations.

(2) The bag leak detection system must be certified by the manufacturer to be capable of detecting PM emissions at concentrations of 10 milligrams per actual cubic meter (0.0044 grains per actual cubic foot) or less.

(3) The bag leak detection system sensor must provide an output of relative PM loadings.

(4) The bag leak detection system must be equipped with a device to continuously record the output signal from the sensor.

(5) The bag leak detection system must be equipped with an audible alarm system that will sound automatically when an increase in relative PM emissions over a preset level is detected. The alarm must be located where it is easily heard by plant operating personnel.

(6) For positive pressure fabric filter systems, a bag leak detector must be installed in each baghouse compartment or cell.

(7) For negative pressure or induced air fabric filters, the bag leak detector must be installed downstream of the fabric filter.

(8) Where multiple detectors are required, the system's instrumentation and alarm may be shared among detectors.

(9) The baseline output must be established by adjusting the range and the averaging period of the device and establishing the alarm set points and the alarm delay time according to section 5.0 of the EPA-454/R-98-015, "Fabric Filter Bag Leak Detection Guidance," (incorporated by reference, see § 63.14).

(10) Following initial adjustment of the system, the sensitivity or range, averaging period, alarm set points, or alarm delay time may not be adjusted except as detailed in your OM&M plan. In no case may the sensitivity be increased by more than 100 percent or

decreased more than 50 percent over a 365-day period unless such adjustment follows a complete fabric filter inspection that demonstrates that the fabric filter is in good operating condition, as defined in section 5.2 of the "Fabric Filter Bag Leak Detection Guidance," (incorporated by reference, see § 63.14). Record each adjustment.

(11) Record the results of each inspection, calibration, and validation check.

(f) For each lime, chemical, or carbon feed rate measurement device, you must meet the requirements in paragraphs (a)(1) through (5) and paragraphs (f)(1) and (2) of this section.

(1) Locate the measurement device in a position that provides a representative feed rate measurement.

(2) At least semiannually, conduct a calibration check.

(g) For each limestone feed system on a dry limestone adsorber (DLA), you must meet the requirements in paragraphs (a)(1), (4), and (5) of this section and must ensure on a monthly basis that the feed system replaces limestone at least as frequently as the schedule set during the performance test.

(h) For each temperature measurement device, you must meet the requirements in paragraphs (a)(1) through (5) and paragraphs (h)(1) through (3) of this section.

(1) Locate the measurement device in a position that provides a representative temperature.

(2) Use a measurement device with a minimum sensitivity of 1 percent of the temperature being measured.

(3) At least semiannually, conduct a calibration check.

(i) Requests for approval of alternate monitoring procedures must meet the requirements in §§ 63.8445(h) and 63.8(f).

**§ 63.8455 How do I demonstrate initial compliance with the emission limitations and work practice standards?**

(a) You must demonstrate initial compliance with each emission limitation and work practice standard that applies to you according to Table 5 to this subpart.

(b) You must establish each site-specific operating limit in Table 2 to this subpart that applies to you according to the requirements in § 63.8445 and Table 4 to this subpart.

(c) You must submit the Notification of Compliance Status containing the results of the initial compliance demonstration according to the requirements in § 63.8480(c).

**Continuous Compliance Requirements**

**§ 63.8465 How do I monitor and collect data to demonstrate continuous compliance?**

(a) You must monitor and collect data according to this section.

(b) Except for periods of monitor malfunctions, associated repairs, and required quality assurance or control activities (including, as applicable, calibration checks and required zero and span adjustments), you must monitor continuously (or collect data at all required intervals) at all times that the affected source is operating. This includes periods of startup, shutdown, malfunction, and routine control device maintenance as specified in § 63.8420(d) when the affected source is operating.

(c) You may not use data recorded during monitoring malfunctions, associated repairs, out-of-control periods, or required quality assurance or control activities for purposes of calculating data averages. You must use all the valid data collected during all other periods in assessing compliance. Any averaging period for which you do not have valid monitoring data and such data are required constitutes a deviation from the monitoring requirements.

**§ 63.8470 How do I demonstrate continuous compliance with the emission limitations and work practice standards?**

(a) You must demonstrate continuous compliance with each emission limit, operating limit, and work practice standard in Tables 1, 2, and 3 to this subpart that applies to you according to the methods specified in Table 6 to this subpart.

(b) For each affected kiln that is subject to the emission limits specified in Table 1 to this subpart and is equipped with an APCD that is not addressed in Table 2 to this subpart, or that is using process changes as a means of meeting the emission limits in Table 1 to this subpart, you must demonstrate continuous compliance with each emission limit in Table 1 to this subpart, and each operating limit established as required in § 63.8445(h)(2) according to the methods specified in your approved alternative monitoring procedures request, as described in §§ 63.8445(h)(1) and 63.8(f).

(c) You must report each instance in which you did not meet each emission limit and each operating limit in this subpart that applies to you. These instances are deviations from the emission limitations in this subpart. These deviations must be reported according to the requirements in § 63.8485(c)(9).

(d) [Reserved]

(e)(1) *VE testing.* You must demonstrate continuous compliance with the operating limits in Table 2 to this subpart for visible emissions (VE) from tunnel kilns that are uncontrolled or equipped with DLA, dry lime injection fabric filter (DIFF), dry lime scrubber/fabric filter (DLS/FF), or other dry control device by monitoring VE at each kiln stack according to the requirements in paragraphs (e)(1)(i) through (v) of this section.

(i) Perform daily VE observations of each kiln stack according to the procedures of Method 22 of 40 CFR part 60, appendix A-7. You must conduct the Method 22 test while the affected source is operating under normal conditions. The duration of each Method 22 test must be at least 15 minutes.

(ii) If VE are observed during any daily test conducted using Method 22 of 40 CFR part 60, appendix A-7, you must promptly conduct an opacity test, according to the procedures of Method 9 of 40 CFR part 60, appendix A-4. If opacity greater than 10 percent is observed, you must initiate and complete corrective actions according to your OM&M plan.

(iii) You may decrease the frequency of Method 22 testing from daily to weekly for a kiln stack if one of the conditions in paragraph (e)(1)(iii)(A) or (B) of this section is met.

(A) No VE are observed in 30 consecutive daily Method 22 tests for any kiln stack; or

(B) No opacity greater than 10 percent is observed during any of the Method 9 tests for any kiln stack.

(iv) If VE are observed during any weekly test and opacity greater than 10 percent is observed in the subsequent Method 9 test, you must promptly initiate and complete corrective actions according to your OM&M plan, resume testing of that kiln stack following Method 22 of 40 CFR part 60, appendix A-7, on a daily basis, as described in paragraph (e)(1)(i) of this section, and maintain that schedule until one of the conditions in paragraph (e)(1)(iii)(A) or (B) of this section is met, at which time you may again decrease the frequency of Method 22 testing to a weekly basis.

(v) If greater than 10 percent opacity is observed during any test conducted using Method 9 of 40 CFR part 60, appendix A-4, you must report these deviations by following the requirements in § 63.8485.

(2) *Alternative to VE testing.* In lieu of meeting the requirements under paragraph (e)(1) of this section, you may conduct a PM test at least once every year following the initial performance test, according to the procedures of

Method 5 of 40 CFR part 60, appendix A-3, and the provisions of § 63.8445(e) and (f)(1).

### Notifications, Reports, and Records

#### § 63.8480 What notifications must I submit and when?

(a) You must submit all of the notifications in §§ 63.7(b) and (c), 63.8(f)(4), and 63.9(b) through (e), (g)(1), and (h) that apply to you, by the dates specified.

(b) You must submit all of the notifications specified in Table 8 to this subpart that apply to you, by the dates specified.

(c) If you are required to conduct a performance test or other initial compliance demonstration as specified in Tables 4 and 5 to this subpart, your Notification of Compliance Status as specified in Table 8 to this subpart must include the information in paragraphs (c)(1) through (3) of this section.

(1) The requirements in § 63.9(h)(2)(i).

(2) The operating limit parameter values established for each affected source with supporting documentation and a description of the procedure used to establish the values.

(3) For each APCD that includes a fabric filter, if a bag leak detection system is used, analysis and supporting documentation demonstrating conformance with EPA guidance and specifications for bag leak detection systems in § 63.8450(e).

#### § 63.8485 What reports must I submit and when?

(a) You must submit each report in Table 9 to this subpart that applies to you.

(b) Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must submit each report by the date in Table 9 to this subpart and as specified in paragraphs (b)(1) through (5) of this section.

(1) The first compliance report must cover the period beginning on the compliance date that is specified for your affected source in § 63.8395 and ending on either June 30 or December 31. The first reporting period must be at least 6 months, but less than 12 months. For example, if your compliance date is March 1, then the first semiannual reporting period would begin on March 1 and end on December 31.

(2) The first compliance report must be postmarked or delivered no later than July 31 or January 31 for compliance periods ending on June 30 and December 31, respectively.

(3) Each subsequent compliance report must cover the semiannual reporting period from January 1 through June 30 or the semiannual reporting period from July 1 through December 31.

(4) Each subsequent compliance report must be postmarked or delivered no later than July 31 or January 31 for compliance periods ending on June 30 and December 31, respectively.

(5) For each affected source that is subject to permitting regulations pursuant to 40 CFR part 70 or 40 CFR part 71, if the permitting authority has established dates for submitting semiannual reports pursuant to 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), you may submit the first and subsequent compliance reports according to the dates the permitting authority has established instead of the dates in paragraphs (b)(1) through (4) of this section.

(c) The compliance report must contain the information in paragraphs (c)(1) through (8) of this section.

(1) Company name and address.

(2) Statement by a responsible official with that official's name, title, and signature, certifying that, based on information and belief formed after reasonable inquiry, the statements and information in the report are true, accurate, and complete.

(3) Date of report and beginning and ending dates of the reporting period.

(4) A description of control device maintenance performed while the control device was offline and the kiln controlled by the control device was operating, including the information specified in paragraphs (c)(4)(i) through (iii) of this section.

(i) The date and time when the control device was shut down and restarted.

(ii) Identification of the kiln that was operating and the number of hours that the kiln operated while the control device was offline.

(iii) A statement of whether or not the control device maintenance was included in your approved routine control device maintenance request developed as specified in § 63.8420(d). If the control device maintenance was included in your approved routine control device maintenance request, then you must report the information in paragraphs (c)(4)(iii)(A) through (C) of this section.

(A) The total amount of time that the kiln controlled by the control device operated during the current semiannual compliance period and during the previous semiannual compliance period.

(B) The amount of time that each kiln controlled by the control device was offline for maintenance covered under the routine control device maintenance alternative standard during the current semiannual compliance period and during the previous semiannual compliance period.

(C) Based on the information recorded under paragraphs (c)(4)(iii)(A) and (B) of this section, compute the annual percent of kiln operating uptime during which the control device was offline for routine maintenance using Equation 7.

$$RM = \frac{DT_p + DT_c}{KU_p + KU_c} (100) \quad (\text{Eq. 7})$$

Where:

RM = Annual percentage of kiln uptime during which control device was offline for routine control device maintenance

DT<sub>p</sub> = Control device downtime claimed under the routine control device maintenance alternative standard for the previous semiannual compliance period

DT<sub>c</sub> = Control device downtime claimed under the routine control device maintenance alternative standard for the current semiannual compliance period

KU<sub>p</sub> = Kiln uptime for the previous semiannual compliance period

KU<sub>c</sub> = Kiln uptime for the current semiannual compliance period

(5) A report of the most recent burner tune-up conducted to comply with the dioxin/furan work practice standard in Table 3 to this subpart.

(6) If there are no deviations from any emission limitations (emission limits or operating limits) that apply to you, the

compliance report must contain a statement that there were no deviations from the emission limitations during the reporting period.

(7) If there were no periods during which the CMS was out-of-control as specified in your OM&M plan, the compliance report must contain a statement that there were no periods during which the CMS was out-of-control during the reporting period.

(8) The first compliance report must contain the startup push rate for each kiln, the minimum APCD inlet temperature for each APCD, and the temperature profile for each kiln without an APCD.

(9) For each deviation that occurs at an affected source, report such events in the compliance report by including the information in paragraphs (c)(9)(i) through (iii) of this section.

(i) The date, time, and duration of the deviation.

(ii) A list of the affected sources or equipment for which the deviation occurred.

(iii) An estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

(d) For each deviation from an emission limitation (emission limit or operating limit) occurring at an affected source where you are using a CMS to comply with the emission limitations in this subpart, you must include the information in paragraphs (c)(1) through (4) and (c)(9), and paragraphs (d)(1) through (11) of this section. This includes periods of startup, shutdown, and routine control device maintenance.

(1) The total operating time of each affected source during the reporting period.

(2) The date and time that each CMS was inoperative, except for zero (low-level) and high-level checks.

(3) The date, time, and duration that each CMS was out-of-control, including the pertinent information in your OM&M plan.

(4) Whether each deviation occurred during routine control device maintenance covered in your approved routine control device maintenance alternative standard or during another period, and the cause of each deviation (including unknown cause, if applicable).

(5) A description of any corrective action taken to return the affected unit to its normal or usual manner of operation.

(6) A breakdown of the total duration of the deviations during the reporting period into those that were due to startup, shutdown, control equipment problems, process problems, other known causes, and other unknown causes.

(7) A summary of the total duration of CMS downtime during the reporting period and the total duration of CMS downtime as a percent of the total source operating time during that reporting period.

(8) A brief description of the process units.

(9) A brief description of the CMS.

(10) The date of the latest CMS certification or audit.

(11) A description of any changes in CMS, processes, or control equipment since the last reporting period.

(e) If you have obtained a title V operating permit according to 40 CFR part 70 or 40 CFR part 71, you must report all deviations as defined in this subpart in the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A). If you submit a compliance report according to Table 9 to this subpart along with, or as part of, the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), and the compliance report includes all required information concerning deviations from any emission limitation (including any operating limit), then submitting the compliance report will satisfy any obligation to report the same deviations in the semiannual monitoring report. However, submitting a compliance report will not otherwise affect any obligation you may have to report deviations from permit requirements to the permitting authority.

(f) Within 60 calendar days after the date of completing each performance test (as defined in § 63.2) required by this subpart, you must submit the results of the performance test following the procedure specified in either paragraph (f)(1) or (f)(2) of this section.

(1) For data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT Web site (<http://www.epa.gov/ttn/chief/ert/index.html>) at the time of the test, you must submit the results of the performance test to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI). (CEDRI can be accessed through the EPA's Central Data Exchange (CDX) (<http://cdx.epa.gov/>)). Performance test data must be submitted in a file format generated through the use of the EPA's ERT or an alternate electronic file format consistent with the extensible markup language (XML) schema listed on the EPA's ERT Web site. If you claim that some of the performance test information being submitted is confidential business information (CBI), you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic media

must be clearly marked as CBI and mailed to U.S. EPA/OAPQS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph.

(2) For data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the test, you must submit the results of the performance test to the Administrator at the appropriate address listed in § 63.13.

#### § 63.8490 What records must I keep?

(a) You must keep the records listed in paragraphs (a)(1) through (3) of this section.

(1) A copy of each notification and report that you submitted to comply with this subpart, including all documentation supporting any Initial Notification or Notification of Compliance Status that you submitted, according to the requirements in § 63.10(b)(2)(xiv).

(2) Records of performance tests as required in § 63.10(b)(2)(viii).

(3) Records relating to control device maintenance and documentation of your approved routine control device maintenance request, if you request to use the alternative standard under § 63.8420(d).

(b) You must keep the records required in Table 6 to this subpart to show continuous compliance with each emission limitation and work practice standard that applies to you.

(c) You must also maintain the records listed in paragraphs (c)(1) through (11) of this section.

(1) For each bag leak detection system, records of each alarm, the time of the alarm, the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken.

(2) For each deviation, record the information in paragraphs (c)(2)(i) through (iv) of this section.

(i) The date, time, and duration of the deviation.

(ii) A list of the affected sources or equipment.

(iii) An estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(iv) Actions taken to minimize emissions in accordance with § 63.8420(b) and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

(3) For each affected source, records of production rates on a fired-product basis.

(4) Records for any approved alternative monitoring or test procedures.

(5) Records of maintenance and inspections performed on the APCD.

(6) Current copies of your OM&M plan, including any revisions, with records documenting conformance.

(7) Logs of the information required in paragraphs (c)(7)(i) through (iii) of this section to document proper operation of your periodic kiln.

(i) Records of the firing time and temperature cycle for each product produced in each periodic kiln. If all periodic kilns use the same time and temperature cycles, one copy may be maintained for each kiln. Reference numbers must be assigned to use in log sheets.

(ii) For each periodic kiln, a log that details the type of product fired in each batch, the corresponding time and temperature protocol reference number, and an indication of whether the appropriate time and temperature cycle was fired.

(iii) For each periodic kiln, a log of the actual tonnage of product fired in the periodic kiln and an indication of whether the tonnage was below the maximum tonnage for that specific kiln.

(8) Logs of the maintenance procedures used to demonstrate compliance with the maintenance requirements of the periodic kiln work practice standards specified in Table 3 to this subpart.

(9) Records of burner tune-ups used to comply with the dioxin/furan work practice standard for tunnel kilns.

(10) For periods of startup and shutdown, records of the following information:

(i) The date, time, and duration of each startup and/or shutdown period, recording the periods when the affected source was subject to the standard applicable to startup and shutdown.

(ii) For periods of startup, the kiln push rate and kiln exhaust temperature prior to the time the kiln exhaust reaches the minimum APCD inlet temperature (for a kiln with an APCD) or the kiln temperature profile is attained (for a kiln with no APCD).

(iii) For periods of shutdown, the kiln push rate and kiln exhaust temperature after the time the kiln exhaust falls below the minimum APCD inlet temperature (for a kiln with an APCD) or the kiln temperature profile is no longer maintained (for a kiln with no APCD).

(11) All site-specific parameters, temperature profiles, and procedures

required to be established or developed according to the applicable work practice standards in Table 3 to this subpart.

**§ 63.8495 In what form and for how long must I keep my records?**

(a) Your records must be in a form suitable and readily available for expeditious review, according to § 63.10(b)(1).

(b) As specified in § 63.10(b)(1), you must keep each record for 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record.

(c) You must keep each record onsite for at least 2 years after the date of each occurrence, measurement, maintenance, corrective action, report, or record, according to § 63.10(b)(1). You may keep the records offsite for the remaining 3 years.

**Other Requirements and Information**

**§ 63.8505 What parts of the General Provisions apply to me?**

Table 10 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.16 apply to you.

**§ 63.8510 Who implements and enforces this subpart?**

(a) This subpart can be implemented and enforced by us, the U.S. EPA, or a delegated authority such as your state, local, or tribal agency. If the U.S. EPA Administrator has delegated authority to your state, local, or tribal agency, then that agency, in addition to the U.S. EPA, has the authority to implement and enforce this subpart. You should contact your U.S. EPA Regional Office to find out if implementation and enforcement of this subpart is delegated to your state, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a state, local, or tribal agency under subpart E of this part, the authorities contained in paragraph (c) of this section are retained by the Administrator of the U.S. EPA and are not transferred to the state, local, or tribal agency.

(c) The authorities that cannot be delegated to state, local, or tribal agencies are as specified in paragraphs (c)(1) through (6) of this section.

(1) Approval of alternatives to the applicability requirements in §§ 63.8385 and 63.8390, the compliance date requirements in § 63.8395, and the non-opacity emission limitations in § 63.8405.

(2) Approval of major changes to test methods under § 63.7(e)(2)(ii) and (f) and as defined in § 63.90.

(3) Approval of major changes to monitoring under § 63.8(f) and as defined in § 63.90.

(4) Approval of major changes to recordkeeping and reporting under § 63.10(f) and as defined in § 63.90.

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

(6) Approval of a routine control device maintenance request under § 63.8420(d).

**§ 63.8515 What definitions apply to this subpart?**

Terms used in this subpart are defined in the Clean Air Act, in § 63.2, and in this section as follows:

*Air pollution control device (APCD)* means any equipment that reduces the quantity of a pollutant that is emitted to the air.

*Bag leak detection system* means an instrument that is capable of monitoring PM loadings in the exhaust of a fabric filter in order to detect bag failures. A bag leak detection system includes, but is not limited to, an instrument that operates on triboelectric, light-scattering, light-transmittance, or other effects to monitor relative PM loadings.

*Brick and structural clay products (BSCP) manufacturing facility* means a plant site that manufactures brick (including, but not limited to, face brick, structural brick, and brick pavers); clay pipe; roof tile; extruded floor and wall tile; and/or other extruded, dimensional clay products. Brick and structural clay products manufacturing facilities typically process raw clay and shale, form the processed materials into bricks or shapes, and dry and fire the bricks or shapes. A plant site that manufactures refractory products, as defined in 40 CFR 63.9824, or clay ceramics, as defined in 40 CFR 63.8665, is not a BSCP manufacturing facility.

*Deviation* means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation (including any operating limit) or work practice standard; or

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart for any affected source required to obtain such a permit.

*Dry lime injection fabric filter (DIFF)* means an APCD that includes continuous injection of hydrated lime or other sorbent into a duct or reaction chamber followed by a fabric filter.

*Dry lime scrubber/fabric filter (DLS/FF)* means an APCD that includes



continuous injection of humidified hydrated lime or other sorbent into a reaction chamber followed by a fabric filter. These systems typically include recirculation of some of the sorbent.

*Dry limestone adsorber (DLA)* means an APCD that includes a limestone storage bin, a reaction chamber that is essentially a packed tower filled with limestone, and may or may not include a peeling drum that mechanically scrapes reacted limestone to regenerate the stone for reuse.

*Emission limitation* means any emission limit or operating limit.

*Fabric filter* means an APCD used to capture PM by filtering a gas stream through filter media; also known as a baghouse.

*Initial startup* means:

(1) For a new or reconstructed tunnel kiln controlled with a DLA, the time at which the temperature in the kiln first reaches 260 °C (500 °F) and the kiln contains product; or

(2) for a new or reconstructed tunnel kiln controlled with a DIFF, DLS/FF, or wet scrubber (WS), the time at which the kiln first reaches a level of production that is equal to 75 percent of the kiln design capacity or 12 months after the affected source begins firing BSCP, whichever is earlier.

*Fired product* means brick or structural clay products that have gone through the firing process via kilns.

*Kiln exhaust process stream* means the portion of the exhaust from a tunnel kiln that exhausts directly to the atmosphere (or to an APCD), rather than to a sawdust dryer.

*Large tunnel kiln* means a tunnel kiln (existing, new, or reconstructed) with a design capacity equal to or greater than 9.07 Mg/hr (10 tph) of fired product.

*Minimum APCD inlet temperature* means the minimum temperature that kiln exhaust can be vented to the APCD that ensures the long-term integrity of the APCD.

*Particulate matter (PM)* means, for purposes of this subpart, emissions of PM that serve as a measure of total particulate emissions, as measured by Method 5 (40 CFR part 60, appendix A–3) or Method 29 (40 CFR part 60, appendix A–8), and as a surrogate for non-mercury metal HAP contained in the particulates including, but not limited to, antimony, arsenic, beryllium, cadmium, chromium, cobalt, lead, manganese, nickel, and selenium.

*Periodic kiln* means a batch firing kiln.

*Plant site* means all contiguous or adjoining property that is under common control, including properties that are separated only by a road or other public right-of-way. Common control includes properties that are owned, leased, or operated by the same entity, parent entity, subsidiary, or any combination thereof.

*Responsible official* means responsible official as defined in 40 CFR 70.2.

*Small tunnel kiln* means a tunnel kiln (existing, new, or reconstructed) with a design capacity less than 9.07 Mg/hr (10 tph) of fired product.

*Startup* means the setting in operation of an affected source and starting the production process.

*Startup push rate* means the kiln push rate required to bring the kiln to the proper operating temperature during startup.

*Tunnel kiln* means any continuous kiln that is used to fire BSCP. Some tunnel kilns have two process streams, including a process stream that exhausts directly to the atmosphere or to an APCD, and a process stream in which the kiln exhaust is ducted to a sawdust dryer where it is used to dry sawdust before being emitted to the atmosphere.

*Tunnel kiln design capacity* means the maximum amount of brick, in Mg (tons), that a kiln is designed to produce in one year divided by the number of hours in a year (8,760 hours), taking into account the void space in the brick, the push rate for the kiln, and the stacking pattern, if applicable. If a kiln is modified to increase the capacity, the design capacity is considered to be the capacity following modifications.

*Wet scrubber (WS)* means an APCD that uses water, which may include caustic additives or other chemicals, as the sorbent. Wet scrubbers may use any of various design mechanisms to increase the contact between exhaust gases and the sorbent.

*Work practice standard* means any design, equipment, work practice, operational standard, or combination thereof, that is promulgated pursuant to section 112(h) of the Clean Air Act.

**Tables to Subpart JJJJJ of Part 63**

As stated in § 63.8405, you must meet each emission limit in the following table that applies to you:

TABLE 1 TO SUBPART JJJJJ OF PART 63—EMISSION LIMITS

For each . . .	You must meet the following emission limits . . .	Or you must comply with the following . . .
1. Collection of all tunnel kilns at facility, including all process streams.	HF, HCl, and Cl <sub>2</sub> emissions must not exceed 26 kg/hr (57 lb/hr) HCl equivalent, under the health-based standard, as determined using Equations 2 and 3.	Not applicable.
2. Existing large tunnel kiln (design capacity ≥10 tons per hour (tph) of fired product), including all process streams.	<p>a. PM emissions must not exceed 0.018 kg/Mg (0.036 lb/ton) of fired product.</p> <p>b. Hg emissions must not exceed 2.1 E–05 kilogram per megagram (kg/Mg) (4.1 E–05 pound per ton (lb/ton)) of fired product.</p>	<p>i. PM emissions must not exceed 6.6 mg/dscm (0.0029 gr/dscf) at 17% O<sub>2</sub>; or</p> <p>ii. Non-Hg HAP metals emissions must not exceed 0.0026 kg/hr (0.0057 lb/hr).</p> <p>i. Hg emissions must not exceed 7.7 micrograms per dry standard cubic meter (µg/dscm) at 17% O<sub>2</sub>; or</p> <p>ii. Hg emissions must not exceed 2.5 E–04 kg/hr (5.5 E–04 lb/hr).</p>
3. Existing small tunnel kiln (design capacity <10 tph of fired product), including all process streams.	<p>a. PM emissions must not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product.</p> <p>b. Hg emissions must not exceed 1.7 E–04 kg/Mg (3.3 E–04 lb/ton) of fired product.</p>	<p>i. PM emissions must not exceed 4.8 mg/dscm (0.0021 gr/dscf) at 17% O<sub>2</sub>; or</p> <p>ii. Non-Hg HAP metals emissions must not exceed 0.047 kg/hr (0.11 lb/hr).</p> <p>i. Hg emissions must not exceed 91 µg/dscm at 17% O<sub>2</sub>; or</p> <p>ii. Hg emissions must not exceed 8.5 E–04 kg/hr (0.0019 lb/hr).</p>

TABLE 1 TO SUBPART JJJJJ OF PART 63—EMISSION LIMITS—Continued

For each . . .	You must meet the following emission limits . . .	Or you must comply with the following . . .
4. New or reconstructed large tunnel kiln (design capacity $\geq$ 10 tph of fired product), including all process streams.	<p>a. PM emissions must not exceed 0.0089 kg/Mg (0.018 lb/ton) of fired product..</p> <p>b. Hg emissions must not exceed 1.4 E-05 kg/Mg (2.8 E-05 lb/ton) of fired product.</p>	<p>i. PM emissions must not exceed 3.2 mg/dscm (0.0014 gr/dscf) at 17% O<sub>2</sub>; or</p> <p>ii. Non-Hg HAP metals emissions must not exceed 0.0026 kg/hr (0.0057 lb/hr) of fired product.</p> <p>i. Hg emissions must not exceed 6.2 <math>\mu</math>g/dscm at 17% O<sub>2</sub>.</p> <p>ii. Hg emissions must not exceed 1.6 E-04 kg/hr (3.4 E-04 lb/hr).</p>
5. New or reconstructed small tunnel kiln (design capacity <10 tph of fired product), including all process streams.	<p>a. PM emissions must not exceed 0.015 kg/Mg (0.030 lb/ton) of fired product.</p> <p>b. Hg emissions must not exceed 1.7 E-04 kg/Mg (3.3 E-04 lb/ton) of fired product.</p>	<p>i. PM emissions must not exceed 4.7 mg/dscm (0.0021 gr/dscf) at 17% O<sub>2</sub>; or</p> <p>ii. Non-Hg HAP metals emissions must not exceed 0.047 kg/hr (0.11 lb/hr) of fired product.</p> <p>i. Hg emissions must not exceed 91 <math>\mu</math>g/dscm at 17% O<sub>2</sub>.</p> <p>ii. Hg emissions must not exceed 8.5 E-04 kg/hr (0.0019 lb/hr).</p>

As stated in § 63.8405, you must meet each operating limit in the following table that applies to you:

TABLE 2 TO SUBPART JJJJJ OF PART 63—OPERATING LIMITS

For each . . .	You must . . .
1. Tunnel kiln equipped with a DLA	<p>a. Maintain the average pressure drop across the DLA for each 3-hour block period at or above the average pressure drop established during the HF/HCl/Cl<sub>2</sub> performance test; or, if you are monitoring the bypass stack damper position, initiate corrective action within 1 hour after the bypass damper is opened allowing the kiln exhaust gas to bypass the DLA and complete corrective action in accordance with your OM&amp;M plan; and</p> <p>b. Maintain an adequate amount of limestone in the limestone hopper, storage bin (located at the top of the DLA), and DLA at all times; maintain the limestone feeder setting (on a per ton of fired product basis) at or above the level established during the HF/HCl/Cl<sub>2</sub> performance test in which compliance was demonstrated; and</p> <p>c. Use the same grade of limestone from the same source as was used during the HF/HCl/Cl<sub>2</sub> performance test in which compliance was demonstrated; maintain records of the source and grade of limestone; and</p> <p>d. Maintain no VE from the DLA stack.</p>
2. Tunnel kiln equipped with a DIFF or DLS/FF.	<p>a. If you use a bag leak detection system, initiate corrective action within 1 hour of a bag leak detection system alarm and complete corrective actions in accordance with your OM&amp;M plan; operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period; or maintain no VE from the DIFF or DLS/FF stack; and</p> <p>b. Maintain free-flowing lime in the feed hopper or silo and to the APCD at all times for continuous injection systems; maintain the feeder setting (on a per ton of fired product basis) at or above the level established during the HF/HCl/Cl<sub>2</sub> performance test for continuous injection systems in which compliance was demonstrated.</p>
3. Tunnel kiln equipped with a WS	<p>a. Maintain the average scrubber liquid pH for each 3-hour block period at or above the average scrubber liquid pH established during the HF/HCl/Cl<sub>2</sub> performance test in which compliance was demonstrated; and</p> <p>b. Maintain the average scrubber liquid flow rate for each 3-hour block period at or above the highest average scrubber liquid flow rate established during the HF/HCl/Cl<sub>2</sub> and PM/non-Hg HAP metals performance tests in which compliance was demonstrated.</p>
4. Tunnel kiln equipped with an ACI system.	Maintain the average carbon flow rate for each 3-hour block period at or above the average carbon flow rate established during the Hg performance test in which compliance was demonstrated.
5. Tunnel kiln with no add-on control.	<p>a. Maintain no VE from the stack.</p> <p>b. Maintain the kiln process rate at or below the kiln process rate determined according to § 63.8445(g)(1).</p>

As stated in § 63.8405, you must meet each work practice standard in the following table that applies to you:

TABLE 3 TO SUBPART JJJJJ OF PART 63—WORK PRACTICE STANDARDS

For each . . .	You must . . .	According to the following requirements . . .
1. Existing, new or reconstructed periodic kiln ..	a. Minimize HAP emissions .....	i. Develop and use a designed firing time and temperature cycle for each periodic kiln. You must either program the time and temperature cycle into your kiln or track each step on a log sheet; and ii. Label each periodic kiln with the maximum load (in tons) of product that can be fired in the kiln during a single firing cycle; and iii. For each firing load, document the total tonnage of product placed in the kiln to ensure that it is not greater than the maximum load identified in item 1b; and iv. Develop and follow maintenance procedures for each kiln that, at a minimum, specify the frequency of inspection and maintenance of temperature monitoring devices, controls that regulate air-to-fuel ratios, and controls that regulate firing cycles; and v. Develop and maintain records for each periodic kiln, as specified in § 63.8490.
2. Existing, new or reconstructed tunnel kiln .....	a. Minimize dioxin/furan emissions .....	i. Maintain and inspect the burners and associated combustion controls (as applicable); and ii. Tune the specific burner type to optimize combustion.
3. Existing, new or reconstructed tunnel kiln during periods of startup.	a. Minimize HAP emissions .....	i. Establish the startup push rate for each kiln, the minimum APCD inlet temperature for each APCD, and temperature profile for each kiln without an APCD and include them in your first compliance report, as specified in § 63.8485(c)(8); and ii. After initial charging of the kiln with loaded kiln cars, remain at or below the startup push rate for the kiln until the kiln exhaust reaches the minimum APCD inlet temperature for a kiln with an APCD or until the kiln temperature profile is attained for a kiln with no APCD; and iii. If your kiln has an APCD, begin venting the exhaust from the kiln through the APCD by the time the kiln exhaust temperature reaches the minimum APCD inlet temperature.
4. Existing, new or reconstructed tunnel kiln during periods of shutdown.	a. Minimize HAP emissions .....	i. Do not push loaded kiln cars into the kiln once the kiln exhaust temperature falls below the minimum APCD inlet temperature if the kiln is controlled by an APCD or when the kiln temperature profile is no longer maintained for an uncontrolled kiln; and ii. If your kiln has an APCD, continue to vent the exhaust from the kiln through the APCD until the kiln exhaust temperature falls below the minimum inlet temperature for the APCD.
5. Existing, new or reconstructed tunnel kiln during periods of routine control device maintenance.	a. Minimize HAP emissions. ....	i. Develop and use a temperature profile for each kiln; and ii. Develop and follow maintenance procedures for each kiln that, at a minimum, specify the frequency of inspection and maintenance of temperature monitoring devices and controls that regulate air-to-fuel ratios; and iii. Develop and maintain records for each kiln, as specified in § 63.8490(a)(3).

As stated in § 63.8445, you must conduct each performance test in the following table that applies to you:

TABLE 4 TO SUBPART JJJJ OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS

For each . . .	You must . . .	Using . . .	According to the following requirements . . .
1. Tunnel kiln .....	<p>a. Select locations of sampling ports and the number of traverse points.</p> <p>b. Determine velocities and volumetric flow rate.</p> <p>c. Conduct gas molecular weight analysis.</p> <p>d. Measure moisture content of the stack gas.</p> <p>e. Measure HF, HCl and Cl<sub>2</sub> emissions.</p> <p>f. Measure PM emissions or non-Hg HAP metals.</p> <p>g. Measure Hg emissions</p>	<p>Method 1 or 1A of 40 CFR part 60, appendix A–1.</p> <p>Method 2 of 40 CFR part 60, appendix A–1.</p> <p>Method 3 of 40 CFR part 60, appendix A–2.</p> <p>Method 4 of 40 CFR part 60, appendix A–3.</p> <p>i. Method 26A of 40 CFR part 60, appendix A–8; or.</p> <p>ii. Method 320 of appendix A of this part.</p> <p>i. For PM only: Method 5 of 40 CFR part 60, appendix A–3; or.</p> <p>ii. For PM or non-Hg HAP metals: Method 29 of 40 CFR part 60, appendix A–8.</p> <p>Method 29 of 40 CFR part 60, appendix A–8.</p>	<p>Sampling sites must be located at the outlet of the APCD and prior to any releases to the atmosphere for all affected sources.</p> <p>You may use Method 2A, 2C, 2D, or 2F of 40 CFR part 60, appendix A–1, or Method 2G of 40 CFR part 60, appendix A–2, as appropriate, as an alternative to using Method 2 of 40 CFR part 60, appendix A–1.</p> <p>You may use Method 3A or 3B of 40 CFR part 60, appendix A–2, as appropriate, as an alternative to using Method 3 of 40 CFR part 60, appendix A–2. ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 63.14) may be used as an alternative to the manual procedures (but not the instrumental procedures) in Methods 3A and 3B.</p> <p>You may use Method 26 of 40 CFR part 60, appendix A–8, as an alternative to using Method 26A of 40 CFR part 60, appendix A–8, when no acid PM (e.g., HF or HCl dissolved in water droplets emitted by sources controlled by a WS) is present. ASTM D6735–01 (Reapproved 2009) (incorporated by reference, see § 63.14) may be used as an alternative to Methods 26 and 26A.</p> <p>When using Method 320 of appendix A of this part, you must follow the analyte spiking procedures of section 13 of Method 320 of appendix A of this part, unless you can demonstrate that the complete spiking procedure has been conducted at a similar source. ASTM D6348–03 (Reapproved 2010) (incorporated by reference, see § 63.14) may be used as an alternative to Method 320 if the test plan preparation and implementation in Annexes A1–A8 are mandatory and the %R in Annex A5 is determined for each target analyte.</p> <p>ASTM D6784–02 (Reapproved 2008) (incorporated by reference, see § 63.14) may be used as an alternative to Method 29 (portion for Hg only).</p> <p>Using the procedures in § 63.8445(g)(1), you must determine the maximum process rate(s) for your kiln(s) that would ensure total facility maximum potential HCl-equivalent emissions remain at or below the HCl-equivalent limit in Table 1 to this subpart. The maximum process rate(s) would become your site-specific process rate operating limit(s).</p> <p>You must measure and record the production rate, on a fired-product basis, of the affected source for each of the three test runs.</p> <p>You must continuously measure the pressure drop across the DLA, determine and record the block average pressure drop values for the three test runs, and determine and record the 3-hour block average of the recorded pressure drop measurements for the three test runs. The average of the three test runs establishes your minimum site-specific pressure drop operating limit.</p>
2. Tunnel kiln with no add-on control.	Establish the operating limit(s) for kiln process rate if the total facility maximum potential HCl-equivalent emissions are greater than the HCl-equivalent limit in Table 1 to this subpart.	HCl-equivalent limit in Table 1 to this subpart and emissions and production data from the HF/HCl/Cl <sub>2</sub> performance test.	
3. Tunnel kiln that is complying with PM and/or Hg production-based emission limits.	Determine the production rate during each PM/Hg test run in order to determine compliance with PM and/or Hg production-based emission limits.	Production data collected during the PM/Hg performance tests (e.g., no. of pushes per hour, no. of bricks per kiln car, weight of a typical fired brick).	
4. Tunnel kiln equipped with a DLA.	a. Establish the operating limit for the average pressure drop across the DLA.	Data from the pressure drop measurement device during the HF/HCl/Cl <sub>2</sub> performance test.	

TABLE 4 TO SUBPART JJJJJ OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS—Continued

For each . . .	You must . . .	Using . . .	According to the following requirements . . .
5. Tunnel kiln equipped with a DIFF or DLS/FF.	b. Establish the operating limit for the limestone feeder setting.	Data from the limestone feeder during the HF/HCl/Cl <sub>2</sub> performance test.	You must ensure that you maintain an adequate amount of limestone in the limestone hopper, storage bin (located at the top of the DLA), and DLA at all times during the performance test. You must establish your limestone feeder setting, on a per ton of fired product basis, one week prior to the performance test and maintain the feeder setting for the one-week period that precedes the performance test and during the performance test.
	c. Document the source and grade of limestone used. Establish the operating limit for the lime feeder setting.	Records of limestone purchase. Data from the lime feeder during the HF/HCl/Cl <sub>2</sub> performance test.	
6. Tunnel kiln equipped with a WS.	a. Establish the operating limit for the average scrubber liquid pH.	Data from the pH measurement device during the performance HF/HCl/Cl <sub>2</sub> performance test.	For continuous lime injection systems, you must ensure that lime in the feed hopper or silo and to the APCD is free-flowing at all times during the performance test and record the feeder setting, on a per ton of fired product basis, for the three test runs. If the feed rate setting varies during the three test runs, determine and record the average feed rate from the three test runs. The average of the three test runs establishes your minimum site-specific feed rate operating limit. You must continuously measure the scrubber liquid pH, determine and record the block average pH values for the three test runs, and determine and record the 3-hour block average of the recorded pH measurements for the three test runs. The average of the three test runs establishes your minimum site-specific liquid pH operating limit.
	b. Establish the operating limit for the average scrubber liquid flow rate.	Data from the flow rate measurement device during the HF/HCl/Cl <sub>2</sub> and PM/non-Hg HAP metals performance tests.	
7. Tunnel kiln equipped with an ACI system.	Establish the operating limit for the average carbon flow rate.	Data from the carbon flow rate measurement conducted during the Hg performance test.	You must continuously measure the scrubber liquid flow rate, determine and record the block average flow rate values for the three test runs, and determine and record the 3-hour block average of the recorded flow rate measurements for the three test runs. The average of the three test runs establishes your minimum site-specific liquid flow rate operating level. If different average wet scrubber liquid flow rate values are measured during the HF/HCl/Cl <sub>2</sub> and PM/non-Hg HAP metals tests, the highest of the average values become your site-specific operating limit. You must measure the carbon flow rate during each test run, determine and record the block average carbon flow rate values for the three test runs, and determine and record the 3-hour block average of the recorded carbon flow rate measurements for the three test runs. The average of the three test runs establishes your minimum site-specific activated carbon flow rate operating limit.

As stated in § 63.8455, you must demonstrate initial compliance with each emission limitation and work practice standard that applies to you according to the following table:

TABLE 5 TO SUBPART JJJJJ OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS

For each . . .	For the following . . .	You have demonstrated initial compliance if . . .
1. Collection of all tunnel kilns at the facility, including all process streams.	a. HF, HCl, and Cl <sub>2</sub> emissions must not exceed 26 kg/hr (57 lb/hr) HCl equivalent.	i. You measure HF, HCl, and Cl <sub>2</sub> emissions for each kiln using Method 26 or 26A of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6735-01 (Reapproved 2009) (incorporated by reference, see § 63.14); or Method 320 of appendix A of this part or its alternative, ASTM D6348-03 (Reapproved 2010) (incorporated by reference, see § 63.14); and

TABLE 5 TO SUBPART JJJJJ OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You have demonstrated initial compliance if . . .
2. Existing large tunnel kiln (design capacity $\geq 10$ tph of fired product), including all process streams.	<p>a. PM emissions must not exceed 0.018 kg/Mg (0.036 lb/ton) of fired product or 6.6 mg/dscm (0.0029 gr/dscf) at 17% O<sub>2</sub>; or.</p> <p>b. Non-Hg HAP metals emissions must not exceed 0.0026 kg/hr (0.0057 lb/hr).</p> <p>c. Hg emissions must not exceed 2.1 E-05 kg/Mg (4.1 E-05 lb/ton) of fired product or 7.7 <math>\mu</math>g/dscm at 17% O<sub>2</sub> or 2.5 E-04 kg/hr (5.5 E-04 lb/hr).</p>	<p>ii. You calculate the HCl-equivalent emissions for each kiln using Equation 2 to this subpart; and</p> <p>iii. You sum the HCl-equivalent values for all kilns at the facility using Equation 3 to this subpart; and</p> <p>iv. The facility total HCl-equivalent does not exceed 26 kg/hr (57 lb/hr).</p> <p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3 or Method 29 of 40 CFR part 60, appendix A-8, over the period of the initial performance test, according to the calculations in § 63.8445(f)(1), do not exceed 0.018 kg/Mg (0.036 lb/ton) of fired product or 6.6 mg/dscm (0.0029 gr/dscf) at 17% O<sub>2</sub>; and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.018 kg/Mg (0.036 lb/ton) of fired product or 6.6 mg/dscm (0.0029 gr/dscf) at 17% O<sub>2</sub>.</p> <p>i. The non-Hg HAP metals emissions measured using Method 29 of 40 CFR part 60, appendix A-8, over the period of the initial performance test, do not exceed 0.0026 kg/hr (0.0057 lb/hr); and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which non-Hg HAP metals emissions did not exceed 0.0026 kg/hr (0.0057 lb/hr).</p> <p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6784-02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 2.1 E-05 kg/Mg (4.1 E-05 lb/ton) of fired product or 7.7 <math>\mu</math>g/dscm at 17% O<sub>2</sub> or 2.5 E-04 kg/hr (5.5 E-04 lb/hr); and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 2.1 E-05 kg/Mg (4.1 E-05 lb/ton) of fired product or 7.7 <math>\mu</math>g/dscm at 17% O<sub>2</sub> or 2.5 E-04 kg/hr (5.5 E-04 lb/hr).</p>
3. Existing small tunnel kiln (design capacity <10 tph of fired product), including all process streams.	a. PM emissions must not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product or 4.8 mg/dscm (0.0021 gr/dscf) at 17% O <sub>2</sub> ; or.	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3 or Method 29 of 40 CFR part 60, appendix A-8, over the period of the initial performance test, according to the calculations in § 63.8445(f)(1), do not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product or 4.8 mg/dscm (0.0021 gr/dscf) at 17% O<sub>2</sub>; and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product or 4.8 mg/dscm (0.0021 gr/dscf) at 17% O<sub>2</sub>.</p>

TABLE 5 TO SUBPART JJJJJ OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You have demonstrated initial compliance if . . .
<p>4. New or reconstructed large tunnel kiln (design capacity <math>\geq 10</math> tph of fired product), including all process streams.</p>	<p>b. Non-Hg HAP metals emissions must not exceed 0.047 kg/hr (0.11 lb/hr).</p>	<p>i. The non-Hg HAP metals emissions measured using Method 29 of 40 CFR part 60, appendix A–8, over the period of the initial performance test, do not exceed 0.047 kg/hr (0.11 lb/hr); and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which non-Hg HAP metals emissions did not exceed 0.047 kg/hr (0.11 lb/hr).</p>
	<p>c. Hg emissions must not exceed 1.7 E–04 kg/Mg (3.3 E–04 lb/ton) of fired product or 91 <math>\mu\text{g/dscm}</math> at 17% O<sub>2</sub> or 8.5 E–04 kg/hr (0.0019 lb/hr).</p>	<p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A–8 or its alternative, ASTM D6784–02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 1.7 E–04 kg/Mg (3.3 E–04 lb/ton) of fired product or 91 <math>\mu\text{g/dscm}</math> at 17% O<sub>2</sub> or 8.5 E–04 kg/hr (0.0019 lb/hr); and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 1.7 E–04 kg/Mg (3.3 E–04 lb/ton) of fired product or 91 <math>\mu\text{g/dscm}</math> at 17% O<sub>2</sub> or 8.5 E–04 kg/hr (0.0019 lb/hr).</p>
	<p>a. PM emissions must not exceed 0.0089 kg/Mg (0.018 lb/ton) of fired product or 3.2 mg/dscm (0.0014 gr/dscf) at 17% O<sub>2</sub>; or.</p>	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A–3, over the period of the initial performance test, according to the calculations in § 63.8445(f)(1), do not exceed 0.0089 kg/Mg (0.018 lb/ton) of fired product or 3.2 mg/dscm (0.0014 gr/dscf) at 17% O<sub>2</sub>; and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.0089 kg/Mg (0.018 lb/ton) of fired product or 3.2 mg/dscm (0.0014 gr/dscf) at 17% O<sub>2</sub>.</p>
<p>b. Non-Hg HAP metals emissions must not exceed 0.0026 kg/hr (0.0057 lb/hr).</p>	<p>i. The non-Hg HAP metals emissions measured using Method 29 of 40 CFR part 60, appendix A–8, over the period of the initial performance test, do not exceed 0.0026 kg/hr (0.0057 lb/hr); and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which non-Hg HAP metals emissions did not exceed 0.0026 kg/hr (0.0057 lb/hr).</p>	
<p>c. Hg emissions must not exceed 1.4 E–05 kg/Mg (2.8 E–05 lb/ton) of fired product or 6.2 <math>\mu\text{g/dscm}</math> at 17% O<sub>2</sub> or 1.6 E–04 kg/hr (3.4 E–04 lb/hr).</p>	<p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A–8 or its alternative, ASTM D6784–02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 1.4 E–05 kg/Mg (2.8 E–05 lb/ton) of fired product or 6.2 <math>\mu\text{g/dscm}</math> at 17% O<sub>2</sub> or 1.6 E–04 kg/hr (3.4 E–04 lb/hr); and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 1.4 E–05 kg/Mg (2.8 E–05 lb/ton) of fired product or 6.2 <math>\mu\text{g/dscm}</math> at 17% O<sub>2</sub> or 1.6 E–04 kg/hr (3.4 E–04 lb/hr).</p>	



TABLE 5 TO SUBPART JJJJJ OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You have demonstrated initial compliance if . . .
5. New or reconstructed small tunnel kiln (design capacity <10 tph of fired product), including all process streams.	<p>a. PM emissions must not exceed 0.015 kg/Mg (0.030 lb/ton) of fired product or 4.7 mg/dscm (0.0021 gr/dscf) at 17% O<sub>2</sub>; or.</p> <p>b. Non-Hg HAP metals emissions must not exceed 0.047 kg/hr (0.11 lb/hr).</p> <p>c. Hg emissions must not exceed 1.7 E-04 kg/Mg (3.3 E-04 lb/ton) of fired product or 91 µg/dscm at 17% O<sub>2</sub> or 8.5 E-04 kg/hr (0.0019 lb/hr).</p>	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3, over the period of the initial performance test, according to the calculations in §63.8445(f)(1), do not exceed 0.015 kg/Mg (0.030 lb/ton) of fired product or 4.7 mg/dscm (0.0021 gr/dscf) at 17% O<sub>2</sub>; and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.015 kg/Mg (0.030 lb/ton) of fired product or 4.7 mg/dscm (0.0021 gr/dscf) at 17% O<sub>2</sub>.</p> <p>i. The non-Hg HAP metals emissions measured using Method 29 of 40 CFR part 60, appendix A-8, over the period of the initial performance test, do not exceed 0.047 kg/hr (0.11 lb/hr); and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which non-Hg HAP metals emissions did not exceed 0.047 kg/hr (0.11 lb/hr).</p> <p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6784-02 (Reapproved 2008) (incorporated by reference, see §63.14), over the period of the initial performance test, do not exceed 1.7 E-04 kg/Mg (3.3 E-04 lb/ton) of fired product or 91 µg/dscm at 17% O<sub>2</sub> or 8.5 E-04 kg/hr (0.0019 lb/hr); and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 1.7 E-04 kg/Mg (3.3 E-04 lb/ton) of fired product or 91 µg/dscm at 17% O<sub>2</sub> or 8.5 E-04 kg/hr (0.0019 lb/hr).</p>
6. Existing, new or reconstructed periodic kiln ..	a. Minimize HAP emissions .....	<p>i. Develop a designed firing time and temperature cycle for each periodic kiln. You must either program the time and temperature cycle into your kiln or track each step on a log sheet; and</p> <p>ii. Label each periodic kiln with the maximum load (in tons) of product that can be fired in the kiln during a single firing cycle; and</p> <p>iii. Develop maintenance procedures for each kiln that, at a minimum, specify the frequency of inspection and maintenance of temperature monitoring devices, controls that regulate air-to-fuel ratios, and controls that regulate firing cycles.</p>
7. Existing, new or reconstructed tunnel kiln .....	a. Minimize dioxin/furan emissions .....	<p>i. Conduct initial inspection of the burners and associated combustion controls (as applicable); and</p> <p>ii. Tune the specific burner type to optimize combustion.</p>

As stated in § 63.8470, you must demonstrate continuous compliance with each emission limitation and work

practice standard that applies to you according to the following table:

TABLE 6 TO SUBPART JJJJJ OF PART 63—CONTINUOUS COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS

For each . . .	For the following . . .	You must demonstrate continuous compliance by . . .
1. Tunnel kiln equipped with a DLA	a. Each emission limit in Table 1 to this subpart and each operating limit in Item 1 of Table 2 to this subpart for tunnel kilns equipped with a DLA.	i. Collecting the DLA pressure drop data according to § 63.8450(a); reducing the DLA pressure drop data to 3-hour block averages according to § 63.8450(a); maintaining the average pressure drop across the DLA for each 3-hour block period at or above the average pressure drop established during the HF/HCl/Cl <sub>2</sub> performance test in which compliance was demonstrated; or continuously monitoring the bypass stack damper position at least once every 15 minutes during normal kiln operation, and initiating corrective action within 1 hour after the bypass damper is opened allowing the kiln exhaust gas to bypass the DLA and completing corrective action in accordance with your OM&M plan; and ii. Verifying that the limestone hopper and storage bin (located at the top of the DLA) contain adequate limestone by performing a daily visual check, which could include one of the following: (1) Conducting a physical check of the hopper; (2) creating a visual access point, such as a window, on the side of the hopper; (3) installing a camera in the hopper that provides continuous feed to a video monitor in the control room; or (4) confirming that load level indicators in the hopper are not indicating the need for additional limestone; and iii. Recording the limestone feeder setting daily (on a per ton of fired product basis) to verify that the feeder setting is being maintained at or above the level established during the HF/HCl/Cl <sub>2</sub> performance test in which compliance was demonstrated; and iv. Using the same grade of limestone from the same source as was used during the HF/HCl/Cl <sub>2</sub> performance test; maintaining records of the source and type of limestone; and v. Performing VE observations of the DLA stack at the frequency specified in § 63.8470(e) using Method 22 of 40 CFR part 60, appendix A-7; maintaining no VE from the DLA stack.
2. Tunnel kiln equipped with a DIFF or DLS/FF.	a. Each emission limit in Table 1 to this subpart and each operating limit in Item 2 of Table 2 to this subpart for tunnel kilns equipped with DIFF or DLS/FF.	i. If you use a bag leak detection system, as prescribed in § 63.8450(e), initiating corrective action within 1 hour of a bag leak detection system alarm and completing corrective actions in accordance with your OM&M plan; operating and maintaining the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period; in calculating this operating time fraction, if inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted; if corrective action is required, each alarm is counted as a minimum of 1 hour; if you take longer than 1 hour to initiate corrective action, the alarm time is counted as the actual amount of time taken by you to initiate corrective action; or performing VE observations of the DIFF or DLS/FF stack at the frequency specified in § 63.8470(e) using Method 22 of 40 CFR part 60, appendix A-7; and maintaining no VE from the DIFF or DLS/FF stack; and ii. Verifying that lime is free-flowing via a load cell, carrier gas/lime flow indicator, carrier gas pressure drop measurement system, or other system; recording all monitor or sensor output, and if lime is found not to be free flowing, promptly initiating and completing corrective actions in accordance with your OM&M plan; recording the feeder setting once during each shift of operation to verify that the feeder setting is being maintained at or above the level established during the HF/HCl/Cl <sub>2</sub> performance test in which compliance was demonstrated.
3. Tunnel kiln equipped with a WS	a. Each emission limit in Table 1 to this subpart and each operating limit in Item 3 of Table 2 to this subpart for tunnel kilns equipped with WS.	i. Collecting the scrubber liquid pH data according to § 63.8450(a); reducing the scrubber liquid pH data to 3-hour block averages according to § 63.8450(a); maintaining the average scrubber liquid pH for each 3-hour block period at or above the average scrubber liquid pH established during the HF/HCl/Cl <sub>2</sub> performance test in which compliance was demonstrated; and ii. Collecting the scrubber liquid flow rate data according to § 63.8450(a); reducing the scrubber liquid flow rate data to 3-hour block averages according to § 63.8450(a); maintaining the average scrubber liquid flow rate for each 3-hour block period at or above the highest average scrubber liquid flow rate established during the HF/HCl/Cl <sub>2</sub> and PM/non-Hg HAP metals performance tests in which compliance was demonstrated.

TABLE 6 TO SUBPART JJJJJ OF PART 63—CONTINUOUS COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You must demonstrate continuous compliance by . . .
4. Tunnel kiln equipped with an ACI system.	Each emission limit in Table 1 to this subpart and each operating limit in Item 4 of Table 2 to this subpart for tunnel kilns equipped with ACI system.	Collecting the carbon flow rate data according to § 63.8450(a); reducing the carbon flow rate data to 3-hour block averages according to § 63.8450(a); maintaining the average carbon flow rate for each 3-hour block period at or above the average carbon flow rate established during the Hg performance test in which compliance was demonstrated.
5. Tunnel kiln with no add-on control.	a. Each emission limit in Table 1 to this subpart and each operating limit in Item 5 of Table 2 to this subpart for tunnel kilns with no add-on control.	i. Performing VE observations of the stack at the frequency specified in § 63.8470(e) using Method 22 of 40 CFR part 60, appendix A–7; and maintaining no VE from the stack.
6. Periodic kiln .....	a. Minimize HAP emissions .....	ii. If your last calculated total facility maximum potential HCl-equivalent was not at or below the health-based standard in Table 1 to this subpart, collecting the kiln process rate data according to § 63.8450(a); reducing the kiln process rate data to 3-hour block averages according to § 63.8450(a); maintaining the average kiln process rate for each 3-hour block period at or below the kiln process rate determined according to § 63.8445(g)(1). i. Using a designed firing time and temperature cycle for each periodic kiln; and ii. For each firing load, documenting the total tonnage of product placed in the kiln to ensure that it is not greater than the maximum load identified in Item 1.a.ii of Table 3 to this subpart; and iii. Following maintenance procedures for each kiln that, at a minimum, specify the frequency of inspection and maintenance of temperature monitoring devices, controls that regulate air-to-fuel ratios, and controls that regulate firing cycles; and iv. Developing and maintaining records for each periodic kiln, as specified in § 63.8490.
7. Tunnel kiln .....	a. Minimize dioxin/furan emissions	i. Maintaining and inspecting the burners and associated combustion controls (as applicable) and tuning the specific burner type to optimize combustion no later than 36 calendar months after the previous tune-up; and ii. Maintaining records of burner tune-ups used to demonstrate compliance with the dioxin/furan work practice standard; and iii. Submitting a report of most recent tune-up conducted with compliance report.

As stated in § 63.8395, you must meet each compliance date in the following table that applies to you:

TABLE 7 TO SUBPART JJJJJ OF PART 63—COMPLIANCE DATES

If you have a(n) . . .	Then you must . . .	No later than . . .
1. New or reconstructed affected source and the initial startup of your affected source is after December 18, 2014, but before December 28, 2015.	Comply with the applicable emission limitations and work practice standards in Tables 1, 2, and 3 to this subpart.	December 28, 2015.
2. New or reconstructed affected source and the initial startup of your affected source is after December 28, 2015.	Comply with the applicable emission limitations and work practice standards in Tables 1, 2, and 3 to this subpart.	Initial startup of your affected source.
3. Existing affected source .....	Comply with the applicable emission limitations and work practice standards in Tables 1, 2, and 3 to this subpart.	December 26, 2018.
4. Existing area source that increases its emissions or its potential to emit such that it becomes a major source of HAP by adding a new affected source or by reconstructing.	Be in compliance with this subpart .....	Initial startup of your affected source as a major source.
5. New area source ( <i>i.e.</i> , an area source for which construction or reconstruction commenced after December 18, 2014) that increases its emissions or its potential to emit such that it becomes a major source of HAP.	Be in compliance with this subpart .....	Initial startup of your affected source as a major source.

As stated in § 63.8480, you must submit each notification that applies to you according to the following table:

TABLE 8 TO SUBPART JJJJJ OF PART 63—DEADLINES FOR SUBMITTING NOTIFICATIONS

If you . . .	You must . . .	No later than . . .	As specified in . . .
1. Start up your affected source before December 28, 2015.	Submit an Initial Notification .....	June 22, 2016 .....	§ 63.9(b)(2).
2. Start up your new or reconstructed affected source on or after December 28, 2015.	Submit an Initial Notification .....	120 calendar days after you become subject to this subpart.	§ 63.9(b)(2).
3. Are required to conduct a performance test.	Submit a notification of intent to conduct a performance test.	60 calendar days before the performance test is scheduled to begin.	§ 63.7(b)(1).
4. Are required to conduct a compliance demonstration that includes a performance test according to the requirements in Table 4 to this subpart.	Submit a Notification of Compliance Status, including the performance test results.	60 calendar days following the completion of the performance test, by the close of business.	§ 63.9(h) and § 63.10(d)(2).
5. Are required to conduct a compliance demonstration required in Table 5 to this subpart that does not include a performance test (i.e., compliance demonstrations for the work practice standards).	Submit a Notification of Compliance Status.	30 calendar days following the completion of the compliance demonstrations, by the close of business.	§ 63.9(h).
6. Request to use the routine control device maintenance alternative standard according to § 63.8420(d).	Submit your request .....	120 calendar days before the compliance date specified in § 63.8395.	

As stated in § 63.8485, you must submit each report that applies to you according to the following table:

TABLE 9 TO SUBPART JJJJJ OF PART 63—REQUIREMENTS FOR REPORTS

You must submit . . .	The report must contain . . .	You must submit the report . . .
1. A compliance report. ....	<p>a. If there are no deviations from any emission limitations (emission limits, operating limits) that apply to you, a statement that there were no deviations from the emission limitations during the reporting period. If there were no periods during which the CMS was out-of-control as specified in your OM&amp;M plan, a statement that there were no periods during which the CMS was out-of-control during the reporting period.</p> <p>b. If you have a deviation from any emission limitation (emission limit, operating limit) during the reporting period, the report must contain the information in § 63.8485(c)(9). If there were periods during which the CMS was out-of-control, as specified in your OM&amp;M plan, the report must contain the information in § 63.8485(d).</p>	<p>Semiannually according to the requirements in § 63.8485(b).</p> <p>Semiannually according to the requirements in § 63.8485(b).</p>

As stated in § 63.8505, you must comply with the General Provisions in §§ 63.1 through 63.16 that apply to you according to the following table:

TABLE 10 TO SUBPART JJJJJ OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART JJJJJ

Citation	Subject	Brief description	Applies to subpart JJJJJ?
§ 63.1 .....	Applicability .....	Initial applicability determination; applicability after standard established; permit requirements; extensions, notifications.	Yes.
§ 63.2 .....	Definitions .....	Definitions for part 63 standards .....	Yes.
§ 63.3 .....	Units and Abbreviations ....	Units and abbreviations for part 63 standards .....	Yes.
§ 63.4 .....	Prohibited Activities .....	Compliance date; circumvention; severability .....	Yes.
§ 63.5 .....	Construction/Reconstruction.	Applicability; applications; approvals .....	Yes.
§ 63.6(a) .....	Applicability .....	General Provisions (GP) apply unless compliance extension; GP apply to area sources that become major.	Yes.

TABLE 10 TO SUBPART JJJJJ OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART JJJJJ—Continued

Citation	Subject	Brief description	Applies to subpart JJJJJ?
§ 63.6(b)(1)–(4)	Compliance Dates for New and Reconstructed sources.	Standards apply at effective date; 3 years after effective date; upon startup; 10 years after construction or reconstruction commences for section 112(f).	Yes.
§ 63.6(b)(5)	Notification	Must notify if commenced construction or reconstruction after proposal.	Yes.
§ 63.6(b)(6)	[Reserved]		No.
§ 63.6(b)(7)	Compliance Dates for New and Reconstructed Area Sources That Become Major.	Area sources that become major must comply with major source standards immediately upon becoming major, regardless of whether required to comply when they were area sources.	Yes.
§ 63.6(c)(1)–(2)	Compliance Dates for Existing Sources.	Comply according to date in subpart, which must be no later than 3 years after effective date; for section 112(f) standards, comply within 90 calendar days of effective date unless compliance extension.	Yes.
§ 63.6(c)(3)–(4)	[Reserved]		No.
§ 63.6(c)(5)	Compliance Dates for Existing Area Sources That Become Major.	Area sources that become major must comply with major source standards by date indicated in subpart or by equivalent time period (for example, 3 years).	Yes.
§ 63.6(d)	[Reserved]		No.
§ 63.6(e)(1)(i)	Operation & Maintenance	General Duty to minimize emissions	No. See § 63.8420(b) for general duty requirement.
§ 63.6(e)(1)(ii)	Operation & Maintenance	Requirement to correct malfunctions ASAP	No.
§ 63.6(e)(1)(iii)	Operation & Maintenance	Operation and maintenance requirements enforceable independent of emissions limitations.	Yes.
§ 63.6(e)(2)	[Reserved]		No.
§ 63.6(e)(3)	Startup, Shutdown, and Malfunction Plan (SSMP).	Requirement for startup, shutdown, and malfunction (SSM) and SSMP; content of SSMP.	No.
§ 63.6(f)(1)	Compliance Except During SSM.	You must comply with emission standards at all times except during SSM.	No.
§ 63.6(f)(2)–(3)	Methods for Determining Compliance.	Compliance based on performance test, operation and maintenance plans, records, inspection.	Yes.
§ 63.6(g)	Alternative Standard	Procedures for getting an alternative standard	Yes.
§ 63.6(h)	Opacity/VE Standards	Requirements for opacity and VE standards	No, not applicable.
§ 63.6(i)	Compliance Extension	Procedures and criteria for Administrator to grant compliance extension.	Yes.
§ 63.6(j)	Presidential Compliance Exemption.	President may exempt source category	Yes.
§ 63.7(a)(1)–(2)	Performance Test Dates	Dates for conducting initial performance testing and other compliance demonstrations for emission limits and work practice standards; must conduct 180 calendar days after first subject to rule.	Yes.
§ 63.7(a)(3)	Section 114 Authority	Administrator may require a performance test under CAA section 114 at any time.	Yes.
§ 63.7(a)(4)	Notification of Delay in Performance Testing Due To Force Majeure.	Must notify Administrator of delay in performance testing due to force majeure.	Yes.
§ 63.7(b)(1)	Notification of Performance Test.	Must notify Administrator 60 calendar days before the test.	Yes.
§ 63.7(b)(2)	Notification of Rescheduling.	Must notify Administrator 5 calendar days before scheduled date of rescheduled date.	Yes.
§ 63.7(c)	Quality Assurance(QA)/ Test Plan.	Requirements; test plan approval procedures; performance audit requirements; internal and external QA procedures for testing.	Yes.
§ 63.7(d)	Testing Facilities	Requirements for testing facilities	Yes.
§ 63.7(e)(1)	Conditions for Conducting Performance Tests.	Cannot conduct performance tests during SSM; not a violation to exceed standard during SSM.	No, § 63.8445 specifies requirements.
§ 63.7(e)(2)–(3)	Conditions for Conducting Performance Tests.	Must conduct according to subpart and EPA test methods unless Administrator approves alternative; must have at least three test runs of at least 1 hour each; compliance is based on arithmetic mean of three runs; conditions when data from an additional test run can be used.	Yes.
§ 63.7(e)(4)	Testing under Section 114	Administrator's authority to require testing under section 114 of the Act.	Yes.
§ 63.7(f)	Alternative Test Method	Procedures by which Administrator can grant approval to use an alternative test method.	Yes.
§ 63.7(g)	Performance Test Data Analysis.	Must include raw data in performance test report; must submit performance test data 60 calendar days after end of test with the notification of compliance status.	Yes.
§ 63.7(h)	Waiver of Tests	Procedures for Administrator to waive performance test.	Yes.

TABLE 10 TO SUBPART JJJJJ OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART JJJJJ—Continued

Citation	Subject	Brief description	Applies to subpart JJJJJ?
§ 63.8(a)(1)	Applicability of Monitoring Requirements.	Subject to all monitoring requirements in subpart .....	Yes.
§ 63.8(a)(2)	Performance Specifications	Performance Specifications in appendix B of 40 CFR part 60 apply.	Yes.
§ 63.8(a)(3)	[Reserved]	.....	No.
§ 63.8(a)(4)	Monitoring with Flares	Requirements for flares in § 63.11 apply .....	No, not applicable.
§ 63.8(b)(1)	Monitoring	Must conduct monitoring according to standard unless Administrator approves alternative.	Yes.
§ 63.8(b)(2)–(3)	Multiple Effluents and Multiple Monitoring Systems.	Specific requirements for installing and reporting on monitoring systems.	Yes.
§ 63.8(c)(1)	Monitoring System Operation and Maintenance.	Maintenance consistent with good air pollution control practices.	Yes.
§ 63.8(c)(1)(i)	Routine and Predictable SSM.	Reporting requirements for SSM when action is described in SSMP.	No.
§ 63.8(c)(1)(ii)	SSM not in SSMP	Reporting requirements for SSM when action is not described in SSMP.	Yes.
§ 63.8(c)(1)(iii)	Compliance with Operation and Maintenance Requirements.	How Administrator determines if source complying with operation and maintenance requirements.	No.
§ 63.8(c)(2)–(3)	Monitoring System Installation.	Must install to get representative emission and parameter measurements.	Yes.
§ 63.8(c)(4)	CMS Requirements	Requirements for CMS .....	No, § 63.8450 specifies requirements.
§ 63.8(c)(5)	Continuous Opacity Monitoring System (COMS) Minimum Procedures.	COMS minimum procedures .....	No, not applicable.
§ 63.8(c)(6)	CMS Requirements	Zero and high level calibration check requirements .....	Yes.
§ 63.8(c)(7)–(8)	CMS Requirements	Out-of-control periods .....	Yes.
§ 63.8(d)(1) and (2)	CMS Quality Control	Requirements for CMS quality control .....	Yes.
§ 63.8(d)(3)	CMS Quality Control	Written procedures for CMS .....	No, § 63.8425(b)(9) specifies requirements
§ 63.8(e)	CMS Performance Evaluation.	Requirements for CMS performance evaluation .....	Yes.
§ 63.8(f)(1)–(5)	Alternative Monitoring Method.	Procedures for Administrator to approve alternative monitoring.	Yes.
§ 63.8(f)(6)	Alternative to Relative Accuracy Test.	Procedures for Administrator to approve alternative relative accuracy test for continuous emissions monitoring systems (CEMS).	No, not applicable.
§ 63.8(g)	Data Reduction	COMS and CEMS data reduction requirements .....	No, not applicable.
§ 63.9(a)	Notification Requirements	Applicability; State delegation .....	Yes.
§ 63.9(b)	Initial Notifications	Requirements for initial notifications.	Yes.
§ 63.9(c)	Request for Compliance Extension.	Can request if cannot comply by date or if installed BACT/LAER.	Yes.
§ 63.9(d)	Notification of Special Compliance Requirements for New Source.	For sources that commence construction between proposal and promulgation and want to comply 3 years after effective date.	Yes.
§ 63.9(e)	Notification of Performance Test.	Notify Administrator 60 calendar days prior .....	Yes.
§ 63.9(f)	Notification of VE/Opaicity Test.	Notify Administrator 30 calendar days prior .....	No, not applicable.
§ 63.9(g)(1)	Additional Notifications When Using CMS.	Notification of performance evaluation .....	Yes.
§ 63.9(g)(2)–(3)	Additional Notifications When Using CMS.	Notification of COMS data use; notification that relative accuracy alternative criterion were exceeded.	No, not applicable.
§ 63.9(h)	Notification of Compliance Status.	Contents; submittal requirements .....	Yes.
§ 63.9(i)	Adjustment of Submittal Deadlines.	Procedures for Administrator to approve change in when notifications must be submitted.	Yes.
§ 63.9(j)	Change in Previous Information.	Must submit within 15 calendar days after the change	Yes.
§ 63.10(a)	Recordkeeping/Reporting ..	Applicability; general information .....	Yes.
§ 63.10(b)(1)	General Recordkeeping Requirements.	General requirements .....	Yes.
§ 63.10(b)(2)(i)	Records Related to SSM ..	Recordkeeping of occurrence and duration of startups and shutdowns.	No.

TABLE 10 TO SUBPART JJJJJ OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART JJJJJ—Continued

Citation	Subject	Brief description	Applies to subpart JJJJJ?
§ 63.10(b)(2)(ii)	Records Related to SSM	Recordkeeping of failures to meet a standard	No. See § 63.8490(c)(2) for recordkeeping of (1) date, time and duration; (2) listing of affected source or equipment, and an estimate of the volume of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure.
§ 63.10(b)(2)(iii)	Records Related to SSM	Maintenance records.	
§ 63.10(b)(2)(iv)–(v)	Records Related to SSM	Actions taken to minimize emissions during SSM	No.
§ 63.10(b)(2)(vi)–(xii) and (xiv).	CMS Records	Records when CMS is malfunctioning, inoperative or out-of-control.	Yes.
§ 63.10(b)(2)(xiii)	Records	Records when using alternative to relative accuracy test.	
§ 63.10(b)(3)	Records	Applicability Determinations	Yes.
§ 63.10(c)(1)–(15)	Records	Additional records for CMS	No, §§ 63.8425 and 63.8490 specify requirements
§ 63.10(d)(1) and (2)	General Reporting Requirements.	Requirements for reporting; performance test results reporting.	Yes.
§ 63.10(d)(3)	Reporting Opacity or VE Observations.	Requirements for reporting opacity and VE	No, not applicable.
§ 63.10(d)(4)	Progress Reports	Must submit progress reports on schedule if under compliance extension.	Yes.
§ 63.10(d)(5)	SSM Reports	Contents and submission.	No. See § 63.8485(c)(9) for malfunction reporting requirements.
§ 63.10(e)(1)–(3)	Additional CMS Reports	Requirements for CMS reporting	No, §§ 63.8425 and 63.8485 specify requirements.
§ 63.10(e)(4)	Reporting COMS data	Requirements for reporting COMS data with performance test data.	No, not applicable.
§ 63.10(f)	Waiver for Recordkeeping/Reporting.	Procedures for Administrator to waive	Yes.
§ 63.11	Flares	Requirement for flares	No, not applicable.
§ 63.12	Delegation	State authority to enforce standards.	
§ 63.13	Addresses	Addresses for reports, notifications, requests	Yes.
§ 63.14	Incorporation by Reference	Materials incorporated by reference	Yes.
§ 63.15	Availability of Information	Information availability; confidential information	Yes.
§ 63.16	Performance Track Provisions.	Requirements for Performance Track member facilities	Yes.

■ 4. Part 63 is amended by revising subpart KKKKK to read as follows:

**Subpart KKKKK—National Emission Standards for Hazardous Air Pollutants for Clay Ceramics Manufacturing**

Sec.

**What This Subpart Covers**

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- 63.8630 What notifications must I submit and when?
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- Table 1 to Subpart KKKKK of Part 63—Emission Limits



Table 2 to Subpart KKKKK of Part 63—  
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Table 3 to Subpart KKKKK of Part 63—Work  
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Table 4 to Subpart KKKKK of Part 63—  
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Table 6 to Subpart KKKKK of Part 63—Initial  
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Table 7 to Subpart KKKKK of Part 63—  
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Table 8 to Subpart KKKKK of Part 63—  
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Subpart KKKKK

## Subpart KKKKK—National Emission Standards for Hazardous Air Pollutants for Clay Ceramics Manufacturing

### What This Subpart Covers

#### § 63.8530 What is the purpose of this subpart?

This subpart establishes national emission limitations and work practice standards for hazardous air pollutants (HAP) emitted from clay ceramics manufacturing facilities. This subpart also establishes requirements to demonstrate initial and continuous compliance with the emission limitations and work practice standards.

#### § 63.8535 Am I subject to this subpart?

You are subject to this subpart if you own or operate a clay ceramics manufacturing facility that is, is located at, or is part of a major source of HAP emissions according to the criteria in paragraphs (a) and (b) of this section.

(a) A clay ceramics manufacturing facility is a plant site that manufactures pressed floor tile, pressed wall tile, other pressed tile, or sanitaryware (e.g., sinks and toilets). Clay ceramics manufacturing facilities typically process clay, shale, and various additives; form the processed materials into tile or sanitaryware shapes; and dry and fire the ceramic products. Glazes are applied to many tile and sanitaryware products. A plant site that manufactures refractory products, as defined in § 63.9824, or brick and structural clay products (BSCP), as defined in § 63.8515, is not a clay ceramics manufacturing facility.

(b) A major source of HAP emissions is any stationary source or group of stationary sources within a contiguous area under common control that emits or has the potential to emit any single HAP at a rate of 9.07 megagrams (10

tons) or more per year or any combination of HAP at a rate of 22.68 megagrams (25 tons) or more per year.

#### § 63.8540 What parts of my plant does this subpart cover?

(a) This subpart applies to each existing, new, or reconstructed affected source at a clay ceramics manufacturing facility.

(b) Each existing, new, or reconstructed ceramic tile roller kiln, sanitaryware tunnel kiln, sanitaryware shuttle kiln, ceramic tile glaze line using glaze spraying, sanitaryware glaze spray booth, ceramic tile spray dryer, and floor tile press dryer is an affected source.

(c) Process units not subject to the requirements of this subpart are listed in paragraphs (c)(1) through (9) of this section.

(1) Tunnel, roller or shuttle kilns that are used exclusively for refriring.

(2) Tunnel, roller or shuttle kilns that are used exclusively for setting glazes on previously fired products.

(3) Glaze spray operations that are used exclusively with those kilns listed in paragraphs (c)(1) and (2) of this section.

(4) Process units listed in paragraphs (c)(1) through (3) of this section that are permitted to, but do not, process first-fire ware, until such time as they begin to process first-fire ware.

(5) Glaze spray operations that on average use wet glazes containing less than 0.1 (weight) percent metal HAP (dry weight basis) per spray booth over an entire calendar year.

(6) Raw material processing and handling.

(7) Wall tile press dryers.

(8) Sanitaryware ware dryers.

(9) Sources covered by subparts JJJJJ and SSSSS of this part.

(d) A source is a new affected source if construction of the affected source began after December 18, 2014, and you met the applicability criteria at the time you began construction.

(e) An affected source is reconstructed if you meet the criteria as defined in § 63.2.

(f) An affected source is existing if it is not new or reconstructed.

#### § 63.8545 When do I have to comply with this subpart?

(a) You must comply with this subpart no later than the compliance dates in Table 8 to this subpart.

(b) You must meet the notification requirements in § 63.8630 according to the schedule in § 63.8630 and in subpart A of this part. Some of the notifications must be submitted before you are required to comply with the emission limitations in this subpart.

## Emission Limitations and Work Practice Standards

#### § 63.8555 What emission limitations and work practice standards must I meet?

(a) You must meet each emission limit in Table 1 to this subpart that applies to you.

(b) You must meet each operating limit in Table 2 to this subpart that applies to you.

(c) You must meet each work practice standard in Table 3 to this subpart that applies to you.

#### § 63.8560 What are my options for meeting the emission limitations and work practice standards?

(a) To meet the emission limitations in Tables 1 and 2 to this subpart, you must use one or more of the options listed in paragraphs (a)(1) and (2) of this section.

(1) *Emissions control system.* Use an emissions capture and collection system and an air pollution control device (APCD) and demonstrate that the resulting emissions meet the emission limits in Table 1 to this subpart, and that the capture and collection system and APCD meet the applicable operating limits in Table 2 to this subpart.

(2) *Process changes.* Use low-HAP raw materials or implement manufacturing process changes and demonstrate that the resulting emissions or emissions reductions meet the emission limits in Table 1 to this subpart.

(b) To meet the work practice standards for affected sanitaryware shuttle kilns, you must comply with the requirements listed in Table 3 to this subpart.

(c) To meet the work practice standards for affected sources during periods of startup and shutdown, you must comply with the requirements listed in Table 3 to this subpart.

## General Compliance Requirements

#### § 63.8570 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the emission limitations (including operating limits) in this subpart at all times, except during periods that you are approved for and in compliance with the alternative standard for routine control device maintenance as specified in paragraph (d) of this section, and except during periods of start-up and shutdown, at which time you must comply with the applicable work practice standard specified in Table 3 to this subpart.

(b) At all times, you must operate and maintain any affected source, including

associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source. During the period between the compliance date specified for your affected source in § 63.8545 and the date upon which continuous monitoring systems (CMS) (e.g., continuous parameter monitoring systems) have been installed and verified and any applicable operating limits have been set, you must maintain a log detailing the operation and maintenance of the process and emissions control equipment.

(c) For each affected source that is subject to the emission limits specified in Table 1 to this subpart, you must prepare and implement a written operation, maintenance, and monitoring (OM&M) plan according to the requirements in § 63.8575.

(d) If you own or operate an affected source that is subject to the emission limits specified in Table 1 to this subpart and must perform routine maintenance on the control device for that affected source, you may bypass the source control device and continue operating the affected source subject to the alternative standard established in this paragraph upon approval by the Administrator and provided you satisfy the conditions listed in paragraphs (d)(1) through (5) of this section.

(1) You must request to use the routine control device maintenance alternative standard from the Administrator no later than 120 calendar days before the compliance date specified in § 63.8545. Your request must justify the need for the routine maintenance on the control device and the time required to accomplish the maintenance activities, describe the maintenance activities and the frequency of the maintenance activities, explain why the maintenance cannot be accomplished during source shutdowns, provide information stating whether the continued operation of the affected source will result in fewer emissions than shutting the source down while the

maintenance is performed, describe how you plan to comply with paragraph (b) of this section during the maintenance, and provide any other documentation required by the Administrator.

(2) The routine control device maintenance must not exceed 4 percent of the annual operating uptime for each affected source.

(3) The request for the routine control device maintenance alternative standard, if approved by the Administrator, must be incorporated by reference in and attached to the affected source's title V permit.

(4) You must minimize HAP emissions during the period when the affected source is operating and the control device is offline by complying with the applicable standard in Table 3 to this subpart.

(5) You must minimize the time period during which the affected source is operating and the control device is offline.

(e) If you own or operate an affected kiln that is subject to the work practice standard specified in Table 3 to this subpart, you must be in compliance with that work practice standard at all times, except during periods of natural gas curtailment or other periods when natural gas is not available.

(f) You must be in compliance with the provisions of subpart A of this part, except as noted in Table 9 to this subpart.

#### **§ 63.8575 What do I need to know about operation, maintenance, and monitoring plans?**

(a) For each affected source that is subject to the emission limits specified in Table 1 to this subpart, you must prepare, implement, and revise as necessary an OM&M plan that includes the information in paragraph (b) of this section. Your OM&M plan must be available for inspection by the delegated authority upon request.

(b) Your OM&M plan must include, as a minimum, the information in paragraphs (b)(1) through (13) of this section.

(1) Each process and APCD to be monitored, the type of monitoring device that will be used, and the operating parameters that will be monitored.

(2) A monitoring schedule that specifies the frequency that the parameter values will be determined and recorded.

(3) The limits for each parameter that represent continuous compliance with the emission limitations in § 63.8555. The limits must be based on values of the monitored parameters recorded during performance tests.

(4) Procedures for the proper operation and routine and long-term maintenance of each APCD, including a maintenance and inspection schedule that is consistent with the manufacturer's recommendations.

(5) Procedures for installing the CMS sampling probe or other interface at a measurement location relative to each affected process unit such that the measurement is representative of control of the exhaust emissions (e.g., on or downstream of the last APCD).

(6) Performance and equipment specifications for the sample interface, the pollutant concentration or parametric signal analyzer, and the data collection and reduction system.

(7) Continuous monitoring system performance evaluation procedures and acceptance criteria (e.g., calibrations).

(8) Procedures for the proper operation and maintenance of monitoring equipment consistent with the requirements in §§ 63.8600 and 63.8(c)(1), (3), (7), and (8).

(9) Continuous monitoring system data quality assurance procedures consistent with the requirements in § 63.8(d)(1) and (2). The owner or operator shall keep these written procedures on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan in § 63.8(d)(2) is revised, the owner or operator shall keep previous (i.e., superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2).

(10) Continuous monitoring system recordkeeping and reporting procedures consistent with the requirements in §§ 63.8635 and 63.8640.

(11) Procedures for responding to operating parameter deviations, including the procedures in paragraphs (b)(11)(i) through (iii) of this section.

(i) Procedures for determining the cause of the operating parameter deviation.

(ii) Actions necessary for correcting the deviation and returning the operating parameters to the allowable limits.

(iii) Procedures for recording the times that the deviation began and ended, and corrective actions were initiated and completed.

(12) Procedures for keeping records to document compliance.

(13) If you operate an affected source and you plan to take the source control device out of service for routine maintenance, as specified in § 63.8570(d), the procedures specified in paragraphs (b)(13)(i) and (ii) of this section.

(i) Procedures for minimizing HAP emissions from the affected source during periods of routine maintenance of the source control device when the affected source is operating and the control device is offline.

(ii) Procedures for minimizing the duration of any period of routine maintenance on the source control device when the affected source is operating and the control device is offline.

(c) Changes to the operating limits in your OM&M plan require a new performance test. If you are revising an operating limit parameter value, you must meet the requirements in paragraphs (c)(1) and (2) of this section.

(1) Submit a notification of performance test to the Administrator as specified in § 63.7(b).

(2) After completing the performance test to demonstrate that compliance with the emission limits can be achieved at the revised operating limit parameter value, you must submit the performance test results and the revised operating limits as part of the Notification of Compliance Status required under § 63.9(h).

(d) If you are revising the inspection and maintenance procedures in your OM&M plan, you do not need to conduct a new performance test.

**Testing and Initial Compliance Requirements**

**§ 63.8585 By what date must I conduct performance tests?**

For each affected source that is subject to the emission limits specified in Table 1 to this subpart, you must conduct performance tests within 180 calendar days after the compliance date that is specified for your source in § 63.8545 and according to the provisions in § 63.7(a)(2).

**§ 63.8590 When must I conduct subsequent performance tests?**

(a) For each affected source that is subject to the emission limits specified in Table 1 to this subpart, you must conduct a performance test before renewing your 40 CFR part 70 operating permit or at least every 5 years following the initial performance test.

(b) You must conduct a performance test when you want to change the parameter value for any operating limit specified in your OM&M plan.

**§ 63.8595 How do I conduct performance tests and establish operating limits?**

(a) You must conduct each performance test in Table 4 to this subpart that applies to you.

(b) Before conducting the performance test, you must install and calibrate all monitoring equipment.

(c) Each performance test must be conducted according to the requirements in § 63.7 and under the specific conditions in Table 4 to this subpart. Stacks to be tested at sanitaryware manufacturing facilities shall be limited to products of

combustion (POC) stacks and those cooling stacks with an oxygen content at or below 20.5 percent.

(d) Performance tests shall be conducted under such conditions as the Administrator specifies to you based on representative performance of the affected source for the period being tested. Representative conditions exclude periods of startup and shutdown. You may not conduct performance tests during periods of malfunction. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(e) You must conduct at least three separate test runs for each performance test required in this section, as specified in § 63.7(e)(3). Each test run must last at least 1 hour.

(f) You must use the data gathered during the performance test and the equations in paragraphs (f)(1) through (4) of this section to determine compliance with the emission limitations.

(1) To determine compliance with the production-based particulate matter (PM) and mercury (Hg) emission limits for ceramic tile roller kilns and sanitaryware tunnel kilns in Table 1 to this subpart, you must calculate your mass emissions per unit of production for each test run using Equation 1:

$$MP = \frac{ER}{P} \tag{Eq. 1}$$

Where:

MP = mass per unit of production, kilograms (pounds) of pollutant per megagram (ton) of throughput

ER = mass emission rate of pollutant (PM or Hg) during each performance test run, kilograms (pounds) per hour

P = production rate during each performance test run, megagrams (tons) of throughput per hour.

(2) To determine compliance with the PM emission limits for ceramic tile glaze lines with glaze spraying and

sanitaryware glaze spray booths in Table 1 to this subpart, you must calculate your mass emissions per unit of first-fire glaze sprayed (dry weight basis) for each test run using Equation 2:

$$MG = \frac{ER}{G} \tag{Eq. 2}$$

Where:

MG = mass per unit of glaze application, kilograms (pounds) of PM per megagram (ton) of first-fire glaze sprayed (dry weight basis)

ER = mass emission rate of PM during each performance test run, kilograms (pounds) per hour

G = glaze application rate during each performance test run, megagrams (tons) of first-fire glaze sprayed per hour (dry weight basis).

(3) To determine compliance with the dioxin/furan emission limits for tunnel and roller kilns, ceramic tile spray

dryers, and floor tile press dryers in Table 1 to this subpart, you must calculate the sum of the 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) toxic equivalents (TEQs) for each test run using Equation 3:

$$TEQ = \frac{\sum_{i=1}^n (M_i \times TEF_i)}{T_r \times P} \quad (\text{Eq. 3})$$

Where:

TEQ = sum of the 2,3,7,8-TCDD TEQs, nanograms per kilogram of throughput processed.

$M_i$  = mass of dioxin or furan congener  $i$  during performance test run, nanograms  
 $TEF_i$  = 2,3,7,8-TCDD toxic equivalency factor (TEF) for congener  $i$ , as provided in Table 5 to this subpart

$n$  = number of congeners included in TEQ  
 $T_r$  = time of performance test run, hours  
 $P$  = production rate during performance test run, kilograms of throughput processed per hour.

(4) To determine compliance with the health-based standard for acid gas HAP for clay ceramics manufacturing

facilities in Table 1 to this subpart, you must:

(i) Calculate the HCl-equivalent emissions for HF and HCl for each tunnel or roller kiln at your facility using Equation 4:

$$E_i = E_{HCl} + \left[ E_{HF} \left( \frac{RfC_{HCl}}{RfC_{HF}} \right) \right] \quad (\text{Eq. 4})$$

Where:

$E_i$  = HCl-equivalent emissions for kiln  $i$ , kilograms (pounds) per hour

$E_{HCl}$  = emissions of HCl, kilograms (pounds) per hour

$E_{HF}$  = emissions of HF, kilograms (pounds) per hour  
 $RfC_{HCl}$  = reference concentration for HCl, 20 micrograms per cubic meter  
 $RfC_{HF}$  = reference concentration for HF, 14 micrograms per cubic meter

(ii) If you have multiple tunnel or roller kilns at your facility, sum the HCl-equivalent values for all tunnel or roller kilns at the facility using Equation 5:

$$E_{total} = \sum_{i=1}^n E_i \quad (\text{Eq. 5})$$

Where:

$E_{total}$  = HCl-equivalent emissions for total of all kilns at facility, kilograms (pounds) per hour

$E_i$  = HCl-equivalent emissions for kiln  $i$ , kilograms (pounds) per hour

$n$  = number of tunnel kilns at facility

(iii) Compare this value to the health-based standard in Table 1 to this subpart.

(g) You must establish each site-specific operating limit in Table 2 to this subpart that applies to you as specified in paragraph (g)(1) of this section and in Table 4 to this subpart.

(1)(i) If you do not have an APCD installed on your tunnel or roller kiln, you must calculate the maximum potential HCl-equivalent emissions for HF and HCl for each tunnel or roller kiln at your facility using Equation 6:

$$E_{max\ i} = (Cap_i) \left[ (MP_{iHCl}) + (MP_{iHF}) \left( \frac{RfC_{HCl}}{RfC_{HF}} \right) \right] \quad (\text{Eq. 6})$$

Where:

$E_{max\ i}$  = maximum potential HCl-equivalent emissions for kiln  $i$ , kilograms (pounds) per hour

$Cap_i$  = design capacity for kiln  $i$ , megagrams (tons) of throughput per hour

$MP_{iHCl}$  = mass of HCl per unit of production for kiln  $i$ , kilograms (pounds) of HCl per megagram (ton) of throughput  
 $MP_{iHF}$  = mass of HF per unit of production for kiln  $i$ , kilograms (pounds) of HF per megagram (ton) of throughput  
 $RfC_{HCl}$  = reference concentration for HCl, 20 micrograms per cubic meter

$RfC_{HF}$  = reference concentration for HF, 14 micrograms per cubic meter

(ii) If you have multiple tunnel or roller kilns at your facility, sum the maximum potential HCl-equivalent values for all tunnel or roller kilns at the facility using Equation 7:

$$E_{max\ total} = \sum_{i=1}^n E_{max\ i} \quad (\text{Eq. 7})$$

Where:

$E_{max\ total}$  = maximum potential HCl-equivalent emissions for total of all kilns at facility, kilograms (pounds) per hour

$E_{max\ i}$  = maximum potential HCl-equivalent emissions for kiln  $i$ , kilograms (pounds) per hour  
 $n$  = number of kilns at facility

(iii) If you have a single tunnel or roller kiln at your facility and the total facility maximum potential HCl-equivalent emissions ( $E_{max\ total}$ ) are greater than the HCl-equivalent limit in

Table 1 to this subpart, you must determine the maximum process rate for the kiln using Equation 8 that would ensure the total facility maximum

potential HCl-equivalent emissions remain at or below the HCl-equivalent limit. The maximum process rate would become your operating limit for process

rate and must be included in your OM&M plan.

$$P_{\max i} = \frac{HCl - eq}{\left[ (MP_{iHCl}) + (MP_{iHF}) \left( \frac{RfC_{HCl}}{RfC_{HF}} \right) \right]} \quad (\text{Eq. 8})$$

Where:

$P_{\max i}$  = maximum process rate for kiln i, megagrams (tons) per hour

HCl-eq = HCl-equivalent limit in Table 1 to this subpart, 62 kilograms (140 pounds) per hour

$MP_{iHCl}$  = mass of HCl per unit of production for kiln i, kilograms (pounds) of HCl per megagram (ton) of throughput

$MP_{iHF}$  = mass of HF per unit of production for kiln i, kilograms (pounds) of HF per megagram (ton) of throughput

$RfC_{HCl}$  = reference concentration for HCl, 20 micrograms per cubic meter

$RfC_{HF}$  = reference concentration for HF, 14 micrograms per cubic meter

(iv) If you have multiple tunnel or roller kilns at your facility and the total facility maximum potential HCl-equivalent emissions ( $E_{\max \text{ total}}$ ) are greater than the HCl-equivalent limit in Table 1 to this subpart, you must determine the combination of maximum process rates that would ensure that total facility maximum potential HCl-equivalent remains at or below the HCl-equivalent limit. The maximum process rates would become your operating limits for process rate and must be included in your OM&M plan.

(2) [Reserved]

(h) For each affected source that is subject to the emission limits specified in Table 1 to this subpart and is equipped with an APCD that is not addressed in Table 2 to this subpart or that is using process changes as a means of meeting the emission limits in Table 1 to this subpart, you must meet the requirements in § 63.8(f) and paragraphs (h)(1) and (2) of this section.

(1) Submit a request for approval of alternative monitoring procedures to the Administrator no later than the notification of intent to conduct a performance test. The request must contain the information specified in paragraphs (h)(1)(i) through (iv) of this section.

(i) A description of the alternative APCD or process changes.

(ii) The type of monitoring device or procedure that will be used.

(iii) The operating parameters that will be monitored.

(iv) The frequency that the operating parameter values will be determined

and recorded to establish continuous compliance with the operating limits.

(2) Establish site-specific operating limits during the performance test based on the information included in the approved alternative monitoring procedures request and, as applicable, as specified in Table 4 to this subpart.

#### § 63.8600 What are my monitoring installation, operation, and maintenance requirements?

(a) You must install, operate, and maintain each CMS according to your OM&M plan and the requirements in paragraphs (a)(1) through (5) of this section.

(1) Conduct a performance evaluation of each CMS according to your OM&M plan.

(2) The CMS must complete a minimum of one cycle of operation for each successive 15-minute period. To have a valid hour of data, you must have at least three of four equally spaced data values (or at least 75 percent if you collect more than four data values per hour) for that hour (not including startup, shutdown, malfunction, out-of-control periods, or periods of routine control device maintenance covered by the routine control device maintenance alternative standard as specified in § 63.8570(d)).

(3) Determine and record the 3-hour block averages of all recorded readings, calculated after every 3 hours of operation as the average of the previous 3 operating hours. To calculate the average for each 3-hour average period, you must have at least 75 percent of the recorded readings for that period (not including startup, shutdown, malfunction, out-of-control periods, or periods of routine control device maintenance covered by the routine control device maintenance alternative standard as specified in § 63.8570(d)).

(4) Record the results of each inspection, calibration, and validation check.

(5) At all times, maintain the monitoring equipment including, but not limited to, maintaining necessary parts for routine repairs of the monitoring equipment.

(b) For each liquid flow measurement device, you must meet the requirements in paragraphs (a)(1) through (5) and paragraphs (b)(1) through (3) of this section.

(1) Locate the flow sensor in a position that provides a representative flowrate.

(2) Use a flow sensor with a minimum measurement sensitivity of 2 percent of the liquid flowrate.

(3) At least semiannually, conduct a flow sensor calibration check.

(c) For each pressure measurement device, you must meet the requirements in paragraphs (a)(1) through (5) and paragraphs (c)(1) through (7) of this section.

(1) Locate the pressure sensor(s) in or as close to a position that provides a representative measurement of the pressure.

(2) Minimize or eliminate pulsating pressure, vibration, and internal and external corrosion.

(3) Use a gauge with a minimum measurement sensitivity of 0.5 inch of water or a transducer with a minimum measurement sensitivity of 1 percent of the pressure range.

(4) Check the pressure tap daily to ensure that it is not plugged.

(5) Using a manometer, check gauge calibration quarterly and transducer calibration monthly.

(6) Any time the sensor exceeds the manufacturer's specified maximum operating pressure range, conduct calibration checks or install a new pressure sensor.

(7) At least monthly, inspect all components for integrity, all electrical connections for continuity, and all mechanical connections for leakage.

(d) For each pH measurement device, you must meet the requirements in paragraphs (a)(1) through (5) and paragraphs (d)(1) through (4) of this section.

(1) Locate the pH sensor in a position that provides a representative measurement of pH.

(2) Ensure the sample is properly mixed and representative of the fluid to be measured.

(3) Check the pH meter's calibration at one point daily.

(4) At least monthly, inspect all components for integrity and all electrical connections for continuity.

(e) For each bag leak detection system, you must meet the requirements in paragraphs (e)(1) through (11) of this section.

(1) Each triboelectric bag leak detection system must be installed, calibrated, operated, and maintained according to the EPA-454/R-98-015, "Fabric Filter Bag Leak Detection Guidance," (incorporated by reference, see § 63.14). Other types of bag leak detection systems must be installed, operated, calibrated, and maintained in a manner consistent with the manufacturer's written specifications and recommendations.

(2) The bag leak detection system must be certified by the manufacturer to be capable of detecting PM emissions at concentrations of 10 milligrams per actual cubic meter (0.0044 grains per actual cubic foot) or less.

(3) The bag leak detection system sensor must provide an output of relative PM loadings.

(4) The bag leak detection system must be equipped with a device to continuously record the output signal from the sensor.

(5) The bag leak detection system must be equipped with an audible alarm system that will sound automatically when an increase in relative PM emissions over a preset level is detected. The alarm must be located where it is easily heard by plant operating personnel.

(6) For positive pressure fabric filter systems, a bag leak detector must be installed in each baghouse compartment or cell.

(7) For negative pressure or induced air fabric filters, the bag leak detector must be installed downstream of the fabric filter.

(8) Where multiple detectors are required, the system's instrumentation and alarm may be shared among detectors.

(9) The baseline output must be established by adjusting the range and the averaging period of the device and establishing the alarm set points and the alarm delay time according to section 5.0 of the "Fabric Filter Bag Leak Detection Guidance," (incorporated by reference, see § 63.14).

(10) Following initial adjustment of the system, the sensitivity or range, averaging period, alarm set points, or alarm delay time may not be adjusted except as detailed in your OM&M plan. In no case may the sensitivity be increased by more than 100 percent or decreased more than 50 percent over a 365-day period unless such adjustment

follows a complete fabric filter inspection which demonstrates that the fabric filter is in good operating condition, as defined in section 5.2 of the "Fabric Filter Bag Leak Detection Guidance," (incorporated by reference, see § 63.14). Record each adjustment.

(11) Record the results of each inspection, calibration, and validation check.

(f) For each lime, chemical, or carbon feed rate measurement device, you must meet the requirements in paragraphs (a)(1) through (5) and paragraphs (f)(1) and (2) of this section.

(1) Locate the measurement device in a position that provides a representative feed rate measurement.

(2) At least semiannually, conduct a calibration check.

(g) For each temperature measurement device, you must meet the requirements in paragraphs (a)(1) through (5) and paragraphs (g)(1) through (3) of this section.

(1) Locate the measurement device in a position that provides a representative temperature.

(2) Use a measurement device with a minimum sensitivity of 1 percent of the temperature being measured.

(3) At least semiannually, conduct a calibration check.

(h) Requests for approval of alternate monitoring procedures must meet the requirements in §§ 63.8595(h) and 63.8(f).

#### **§ 63.8605 How do I demonstrate initial compliance with the emission limitations and work practice standards?**

(a) You must demonstrate initial compliance with each emission limitation and work practice standard that applies to you according to Table 6 to this subpart.

(b) You must establish each site-specific operating limit in Table 2 to this subpart that applies to you according to the requirements in § 63.8595 and Table 4 to this subpart.

(c) You must submit the Notification of Compliance Status containing the results of the initial compliance demonstration according to the requirements in § 63.8630(e).

#### **Continuous Compliance Requirements**

#### **§ 63.8615 How do I monitor and collect data to demonstrate continuous compliance?**

(a) You must monitor and collect data according to this section.

(b) Except for periods of monitor malfunctions, associated repairs, and required quality assurance or control activities (including, as applicable, calibration checks and required zero and span adjustments), you must

monitor continuously (or collect data at all required intervals) at all times that the affected source is operating. This includes periods of startup, shutdown, malfunction, and routine control device maintenance as specified in § 63.8570(d) when the affected source is operating.

(c) You may not use data recorded during monitoring malfunctions, associated repairs, out-of-control periods, or required quality assurance or control activities for purposes of calculating data averages. You must use all the valid data collected during all other periods in assessing compliance. Any averaging period for which you do not have valid monitoring data and such data are required constitutes a deviation from the monitoring requirements.

#### **§ 63.8620 How do I demonstrate continuous compliance with the emission limitations and work practice standards?**

(a) You must demonstrate continuous compliance with each emission limit, operating limit, and work practice standard in Tables 1, 2, and 3 to this subpart that applies to you according to the methods specified in Table 7 to this subpart.

(b) For each affected source that is subject to the emission limits specified in Table 1 to this subpart and is equipped with an APCD that is not addressed in Table 2 to this subpart, or that is using process changes as a means of meeting the emission limits in Table 1 to this subpart, you must demonstrate continuous compliance with each emission limit in Table 1 to this subpart, and each operating limit established as required in § 63.8595(h)(2) according to the methods specified in your approved alternative monitoring procedures request, as described in §§ 63.8595(h)(1) and 63.8(f).

(c) You must report each instance in which you did not meet each emission limit and operating limit in this subpart that applies to you. These instances are deviations from the emission limitations in this subpart. These deviations must be reported according to the requirements in § 63.8635(c)(8).

(d) [Reserved]

(e) You must demonstrate continuous compliance with the operating limits in Table 2 to this subpart for visible emissions (VE) from tunnel or roller kilns that are uncontrolled or equipped with DIFF, DLS/FF, or other dry control device by monitoring VE at each kiln stack according to the requirements in paragraphs (e)(1) through (3) of this section.

(1) Perform daily VE observations of each kiln stack according to the procedures of Method 22 of 40 CFR part 60, appendix A-7. You must conduct

the Method 22 test while the affected source is operating under normal conditions. The duration of each Method 22 test must be at least 15 minutes.

(2) If VE are observed during any daily test conducted using Method 22 of 40 CFR part 60, appendix A-7, you must promptly initiate and complete corrective actions according to your OM&M plan. If no VE are observed in 30 consecutive daily Method 22 tests for any kiln stack, you may decrease the frequency of Method 22 testing from daily to weekly for that kiln stack. If VE are observed during any weekly test, you must promptly initiate and complete corrective actions according to your OM&M plan, resume Method 22 testing of that kiln stack on a daily basis, and maintain that schedule until no VE are observed in 30 consecutive daily tests, at which time you may again decrease the frequency of Method 22 testing to a weekly basis.

(3) If VE are observed during any test conducted using Method 22 of 40 CFR part 60, appendix A-7, you must report these deviations by following the requirements in § 63.8635.

#### Notifications, Reports, and Records

##### § 63.8630 What notifications must I submit and when?

(a) You must submit all of the notifications in §§ 63.7(b) and (c), 63.8(f)(4), and 63.9 (b) through (e), (g)(1), and (h) that apply to you, by the dates specified.

(b) You must submit all of the notifications specified in Table 9 to this subpart that apply to you, by the dates specified.

(c) If you are required to conduct a performance test or other initial compliance demonstration as specified in Tables 4 and 6 to this subpart, your Notification of Compliance Status as specified in Table 9 to this subpart must include the information in paragraphs (c)(1) through (3) of this section.

(1) The requirements in § 63.9(h)(2)(i).

(2) The operating limit parameter values established for each affected source with supporting documentation and a description of the procedure used to establish the values.

(3) For each APCD that includes a fabric filter, if a bag leak detection system is used, analysis and supporting documentation demonstrating conformance with EPA guidance and specifications for bag leak detection systems in § 63.8600(e).

(d) If you own or operate an affected kiln that is subject to the work practice standard specified in Item 1 of Table 3

to this subpart, and you intend to use a fuel other than natural gas or equivalent to fire the affected kiln, your notification of alternative fuel use must include the information specified in paragraphs (d)(1) through (5) of this section.

(1) Company name and address.

(2) Identification of the affected kiln.

(3) Reason you are unable to use natural gas or equivalent fuel, including the date when the natural gas curtailment was declared or the natural gas supply interruption began.

(4) Type of alternative fuel that you intend to use.

(5) Dates when the alternative fuel use is expected to begin and end.

##### § 63.8635 What reports must I submit and when?

(a) You must submit each report in Table 10 to this subpart that applies to you.

(b) Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must submit each report by the date in Table 10 to this subpart and as specified in paragraphs (b)(1) through (5) of this section.

(1) The first compliance report must cover the period beginning on the compliance date that is specified for your affected source in § 63.8545 and ending on either June 30 or December 31. This reporting period must be at least 6 months, but less than 12 months. For example, if your compliance date is March 1, then the first semiannual reporting period would begin on March 1 and end on December 31.

(2) The first compliance report must be postmarked or delivered no later than July 31 or January 31 for compliance periods ending on June 30 and December 31, respectively.

(3) Each subsequent compliance report must cover the semiannual reporting period from January 1 through June 30 or the semiannual reporting period from July 1 through December 31.

(4) Each subsequent compliance report must be postmarked or delivered no later than July 31 or January 31 for compliance periods ending on June 30 and December 31, respectively.

(5) For each affected source that is subject to permitting regulations pursuant to 40 CFR part 70 or 40 CFR part 71, and if the permitting authority has established dates for submitting semiannual reports pursuant to 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), you may submit the first and subsequent compliance reports

according to the dates the permitting authority has established instead of the dates in paragraphs (b)(1) through (4) of this section.

(c) The compliance report must contain the information in paragraphs (c)(1) through (8) of this section.

(1) Company name and address.

(2) Statement by a responsible official with that official's name, title, and signature, certifying that, based on information and belief formed after reasonable inquiry, the statements and information in the report are true, accurate, and complete.

(3) Date of report and beginning and ending dates of the reporting period.

(4) A description of control device maintenance performed while the control device was offline and the affected source controlled by the control device was operating, including the information specified in paragraphs (c)(4)(i) through (iii) of this section.

(i) The date and time when the control device was shut down and restarted.

(ii) Identification of the affected source that was operating and the number of hours that the affected source operated while the control device was offline.

(iii) A statement of whether or not the control device maintenance was included in your approved routine control device maintenance request developed as specified in § 63.8570(d). If the control device maintenance was included in your approved routine control device maintenance request, then you must report the information in paragraphs (c)(4)(iii)(A) through (C) of this section.

(A) The total amount of time that the affected source controlled by the control device operated during the current semiannual compliance period and during the previous semiannual compliance period.

(B) The amount of time that each affected source controlled by the control device operated while the control device was offline for maintenance covered under the routine control device maintenance alternative standard during the current semiannual compliance period and during the previous semiannual compliance period.

(C) Based on the information recorded under paragraphs (c)(4)(iii)(A) and (B) of this section, compute the annual percent of affected source operating uptime during which the control device was offline for routine maintenance using Equation 9.

$$RM = \frac{DT_p + DT_c}{SU_p + SU_c} (100) \quad (\text{Eq. } 9)$$

Where:

RM = Annual percentage of affected source uptime during which control device was offline for routine control device maintenance

DT<sub>p</sub> = Control device downtime claimed under the routine control device maintenance alternative standard for the previous semiannual compliance period

DT<sub>c</sub> = Control device downtime claimed under the routine control device maintenance alternative standard for the current semiannual compliance period

SU<sub>p</sub> = Affected source uptime for the previous semiannual compliance period

SU<sub>c</sub> = Affected source uptime for the current semiannual compliance period

(5) If there are no deviations from any emission limitations (emission limits or operating limits) or work practice standards that apply to you, the compliance report must contain a statement that there were no deviations from the emission limitations or work practice standards during the reporting period.

(6) If there were no periods during which the CMS was out-of-control as specified in your OM&M plan, the compliance report must contain a statement that there were no periods during which the CMS was out-of-control during the reporting period.

(7) The first compliance report must contain the startup production rate for each ceramic tile roller kiln, floor tile press dryer, ceramic tile spray dryer, and sanitaryware tunnel kiln; the minimum APCD inlet temperature for each APCD; and the temperature profile for each ceramic tile roller kiln, floor tile press dryer, ceramic tile spray dryer, and sanitaryware tunnel kiln without an APCD.

(8) For each deviation that occurs at an affected source, report such events in the compliance report by including the information in paragraphs (c)(8)(i) through (iii) of this section.

(i) The date, time, and duration of the deviation.

(ii) A list of the affected sources or equipment for which the deviation occurred.

(iii) An estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

(d) For each deviation from an emission limitation (emission limit or operating limit) occurring at an affected source where you are using a CMS to comply with the emission limitations in this subpart, you must include the

information in paragraphs (c)(1) through (4) and (c)(8), and paragraphs (d)(1) through (11) of this section. This includes periods of startup, shutdown, and routine control device maintenance.

(1) The total operating time of each affected source during the reporting period.

(2) The date and time that each CMS was inoperative, except for zero (low-level) and high-level checks.

(3) The date, time, and duration that each CMS was out-of-control, including the pertinent information in your OM&M plan.

(4) Whether each deviation occurred during routine control device maintenance covered in your approved routine control device maintenance alternative standard or during another period, and the cause of each deviation (including unknown cause, if applicable).

(5) A description of any corrective action taken to return the affected unit to its normal or usual manner of operation.

(6) A breakdown of the total duration of the deviations during the reporting period into those that are due to startup, shutdown, control equipment problems, process problems, other known causes, and other unknown causes.

(7) A summary of the total duration of CMS downtime during the reporting period and the total duration of CMS downtime as a percent of the total source operating time during that reporting period.

(8) A brief description of the process units.

(9) A brief description of the CMS.

(10) The date of the latest CMS certification or audit.

(11) A description of any changes in CMS, processes, or control equipment since the last reporting period.

(e) If you have obtained a title V operating permit according to 40 CFR part 70 or 40 CFR part 71, you must report all deviations as defined in this subpart in the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A). If you submit a compliance report according to Table 8 to this subpart along with, or as part of, the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), and the compliance report includes all required information concerning deviations from any emission limitation (including any operating limit), then submitting the

compliance report will satisfy any obligation to report the same deviations in the semiannual monitoring report. However, submitting a compliance report will not otherwise affect any obligation you may have to report deviations from permit requirements to the permitting authority.

(f) If you own or operate an affected kiln that is subject to the work practice standard specified in Item 1 of Table 3 to this subpart, and you use a fuel other than natural gas or equivalent to fire the affected kiln, you must submit a report of alternative fuel use within 10 working days after terminating the use of the alternative fuel. The report must include the information in paragraphs (f)(1) through (6) of this section.

(1) Company name and address.

(2) Identification of the affected kiln.

(3) Reason for using the alternative fuel.

(4) Type of alternative fuel used to fire the affected kiln.

(5) Dates that the use of the alternative fuel started and ended.

(6) Amount of alternative fuel used.

(g) Within 60 calendar days after the date of completing each performance test (as defined in § 63.2) required by this subpart, you must submit the results of the performance test following the procedure specified in either paragraph (g)(1) or (g)(2) of this section.

(1) For data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT Web site (<http://www.epa.gov/ttn/chief/ert/index.html>) at the time of the test, you must submit the results of the performance test to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI). (CEDRI can be accessed through the EPA's Central Data Exchange (CDX) (<http://cdx.epa.gov/>)). Performance test data must be submitted in a file format generated through the use of the EPA's ERT or an alternate electronic file format consistent with the extensible markup language (XML) schema listed on the EPA's ERT Web site. If you claim that some of the performance test information being submitted is confidential business information (CBI), you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive, or other



commonly used electronic storage media to the EPA. The electronic media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404-02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph.

(2) For data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the test, you must submit the results of the performance test to the Administrator at the appropriate address listed in § 63.13.

#### **§ 63.8640 What records must I keep?**

(a) You must keep the records listed in paragraphs (a)(1) through (3) of this section.

(1) A copy of each notification and report that you submitted to comply with this subpart, including all documentation supporting any Initial Notification or Notification of Compliance Status that you submitted, according to the requirements in § 63.10(b)(2)(xiv).

(2) Records of performance tests as required in § 63.10(b)(2)(viii).

(3) Records relating to control device maintenance and documentation of your approved routine control device maintenance request, if you request to use the alternative standard under § 63.8570(d).

(b) You must keep the records required in Table 7 to this subpart to show continuous compliance with each emission limitation and work practice standard that applies to you.

(c) You must also maintain the records listed in paragraphs (c)(1) through (10) of this section.

(1) For each bag leak detection system, records of each alarm, the time of the alarm, the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken.

(2) For each deviation, record the information in paragraphs (c)(2)(i) through (iv) of this section.

(i) The date, time, and duration of the deviation.

(ii) A list of the affected sources or equipment.

(iii) An estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(iv) Actions taken to minimize emissions in accordance with § 63.8570(b) and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

(3) For each affected source, records of production rates on a ton throughput processed basis.

(4) Records for any approved alternative monitoring or test procedures.

(5) Records of maintenance and inspections performed on the APCD.

(6) Current copies of your OM&M plan, including any revisions, with records documenting conformance.

(7) Logs of the information required in paragraphs (c)(7)(i) through (iii) of this section to document proper operation of your sanitaryware shuttle kiln.

(i) Records of the firing time and temperature cycle for each sanitaryware shuttle kiln. If all shuttle kilns use the same time and temperature cycles, one copy may be maintained for each kiln. Reference numbers must be assigned to use in log sheets.

(ii) For each sanitaryware shuttle kiln, a log that details the time and temperature protocol reference number, and an indication of whether the appropriate time and temperature cycle was fired.

(iii) For each sanitaryware shuttle kiln, a log of the actual tonnage of greenware fired in the shuttle kiln and an indication of whether the tonnage was below the maximum tonnage for that specific kiln.

(8) Logs of the maintenance procedures used to demonstrate compliance with the maintenance requirements of the sanitaryware shuttle kiln work practice standards specified in Table 3 to this subpart.

(9) For periods of startup and shutdown, records of the following information:

(i) The date, time, and duration of each startup and/or shutdown period, recording the periods when the affected source was subject to the standard applicable to startup and shutdown.

(ii) For periods of startup, the production rate and exhaust temperature prior to the time the exhaust reaches the minimum APCD inlet temperature (for ceramic tile roller kilns, floor tile press dryers, ceramic tile spray dryers, and sanitaryware tunnel kilns with an APCD) or the temperature profile is attained (for ceramic tile roller kilns, floor tile press dryers, ceramic tile spray dryers, and sanitaryware tunnel kilns with no APCD).

(iii) For periods of shutdown, the production rate and exhaust temperature after the time the exhaust falls below the minimum APCD inlet temperature (for ceramic tile roller kilns, floor tile press dryers, ceramic tile spray dryers, and sanitaryware tunnel kilns with an APCD) or the temperature profile is no longer maintained (for

ceramic tile roller kilns, floor tile press dryers, ceramic tile spray dryers, and sanitaryware tunnel kilns with no APCD).

(10) All site-specific parameters, temperature profiles, and procedures required to be established or developed according to the applicable work practice standards in Table 3 to this subpart.

#### **§ 63.8645 In what form and for how long must I keep my records?**

(a) Your records must be in a form suitable and readily available for expeditious review, according to § 63.10(b)(1).

(b) As specified in § 63.10(b)(1), you must keep each record for 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record.

(c) You must keep each record onsite for at least 2 years after the date of each occurrence, measurement, maintenance, corrective action, report, or record, according to § 63.10(b)(1). You may keep the records offsite for the remaining 3 years.

#### **Other Requirements and Information**

##### **§ 63.8655 What parts of the General Provisions apply to me?**

Table 11 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.16 apply to you.

##### **§ 63.8660 Who implements and enforces this subpart?**

(a) This subpart can be implemented and enforced by us, the U.S. EPA, or a delegated authority such as your state, local, or tribal agency. If the U.S. EPA Administrator has delegated authority to your state, local, or tribal agency, then that agency, in addition to the U.S. EPA, has the authority to implement and enforce this subpart. You should contact your U.S. EPA Regional Office to find out if implementation and enforcement of this subpart is delegated to your state, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a state, local, or tribal agency under subpart E of this part, the authorities contained in paragraph (c) of this section are retained by the Administrator of the U.S. EPA and are not transferred to the state, local, or tribal agency.

(c) The authorities that cannot be delegated to state, local, or tribal agencies are as specified in paragraphs (c)(1) through (6) of this section.

(1) Approval of alternatives to the applicability requirements in §§ 63.8535 and 63.8540, the compliance date requirements in § 63.8545, and the non-

opacity emission limitations in § 63.8555.

(2) Approval of major changes to test methods under § 63.7(e)(2)(ii) and (f) and as defined in § 63.90.

(3) Approval of major changes to monitoring under § 63.8(f) and as defined in § 63.90.

(4) Approval of major changes to recordkeeping and reporting under § 63.10(f) and as defined in § 63.90.

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

(6) Approval of a routine control device maintenance request under § 63.8570(d).

#### § 63.8665 What definitions apply to this subpart?

Terms used in this subpart are defined in the Clean Air Act, in § 63.2, and in this section as follows:

*Air pollution control device (APCD)* means any equipment that reduces the quantity of a pollutant that is emitted to the air.

*Bag leak detection system* means an instrument that is capable of monitoring PM loadings in the exhaust of a fabric filter in order to detect bag failures. A bag leak detection system includes, but is not limited to, an instrument that operates on triboelectric, light-scattering, light-transmittance, or other effects to monitor relative PM loadings.

*Clay ceramics manufacturing facility* means a plant site that manufactures pressed floor tile, pressed wall tile, other pressed tile, or sanitaryware (e.g., sinks and toilets). Clay ceramics manufacturing facilities typically process clay, shale, and various additives, form the processed materials into tile or sanitaryware shapes, and dry and fire the ceramic products. Glazes are applied to many tile and sanitaryware products. A plant site that manufactures refractory products, as defined in § 63.9824, or brick and structural clay products (BSCP), as defined in § 63.8515, is not a clay ceramics manufacturing facility.

*Deviation* means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation (including any operating limit) or work practice standard; or

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart for any affected source required to obtain such a permit.

*Dioxin/furan* means, for purposes of this subpart, the sum of the 2,3,7,8-

TCDD toxic equivalents calculated using Equation 3 of this subpart.

*Dry lime injection fabric filter (DIFF)* means an APCD that includes continuous injection of hydrated lime or other sorbent into a duct or reaction chamber followed by a fabric filter.

*Dry lime scrubber/fabric filter (DLS/FF)* means an APCD that includes continuous injection of humidified hydrated lime or other sorbent into a reaction chamber followed by a fabric filter. These systems typically include recirculation of some of the sorbent.

*Emission limitation* means any emission limit or operating limit.

*Fabric filter* means an APCD used to capture PM by filtering a gas stream through filter media; also known as a baghouse.

*Fired product* means clay ceramic or sanitaryware products that have gone through the firing process via kilns.

*Glaze* means a coating of colored, opaque, or transparent material applied to ceramic products before firing.

*Glaze line* means a production line for glazing ceramic products, which includes glaze spraying (typically comprised of one or more glaze spray booths) and other types of glazing operations (e.g., dipping, flooding, centrifugal disc glazing, curtain coating).

*Glaze spray booth* means a type of equipment used for spraying glaze on ceramic products.

*Glaze spray operation* means any type of glaze application that uses glaze spraying, including glaze lines and glaze spray booths.

*Greenware* means clay ceramic or sanitaryware products that have not gone through the firing process via kilns.

*Initial startup* means the time at which the kiln first reaches a level of production that is equal to 75 percent of the kiln design capacity or 12 months after the affected source begins firing clay ceramics, whichever is earlier.

*Kiln design capacity* means the maximum amount of clay ceramics, in Mg (tons), that a kiln is designed to produce in one year divided by the number of hours in a year (8,760 hours), taking into account the void space in the product, the push rate for the kiln, and the stacking pattern, if applicable. If a kiln is modified to increase the capacity, the design capacity is considered to be the capacity following modifications.

*Minimum APCD inlet temperature* means the minimum temperature that kiln exhaust can be vented to the APCD that ensures the long-term integrity of the APCD.

*Particulate matter (PM)* means, for purposes of this subpart, emissions of

filterable PM that serve as a measure of total particulate emissions, as measured by Method 5 (40 CFR part 60, appendix A-3) or Method 29 (40 CFR part 60, appendix A-8), and as a surrogate for non-mercury metal HAP contained in the particulates including, but not limited to, antimony, arsenic, beryllium, cadmium, chromium, cobalt, lead, manganese, nickel, and selenium.

*Period of natural gas curtailment or supply interruption* means a period of time during which the supply of natural gas to an affected facility is halted for reasons beyond the control of the facility. An increase in the cost or unit price of natural gas does not constitute a period of natural gas curtailment or supply interruption.

*Plant site* means all contiguous or adjoining property that is under common control, including properties that are separated only by a road or other public right-of-way. Common control includes properties that are owned, leased, or operated by the same entity, parent entity, subsidiary, or any combination thereof.

*Responsible official* means responsible official as defined in 40 CFR 70.2.

*Roller kiln* means a continuous kiln similar to a tunnel kiln except that the unfired ceramic product travels through the kiln in a single layer on rollers. In the clay ceramics source category, roller kilns are used at ceramic tile manufacturing plants.

*Shuttle kiln* means a batch firing kiln that is designed with a removable superstructure that is tilted or raised using hydraulic struts to allow entrance and egress. In the clay ceramics source category, shuttle kilns are used at sanitaryware manufacturing plants.

*Spray dryer* means a drying chamber used to form a free-flowing powder from a slurry of ceramic mix and water, to improve handling and compaction. In the clay ceramics source category, spray dryers are used at ceramic tile manufacturing plants.

*Startup* means the setting in operation of an affected source and starting the production process.

*Startup production rate* means the kiln, press dryer or spray dryer production rate required to bring the process unit to the proper operating temperature during startup.

*Tunnel kiln* means any continuous kiln that is not a roller kiln that is used to fire clay ceramics. In the clay ceramics source category, tunnel kilns are used at sanitaryware manufacturing plants.

*Wet scrubber (WS)* means an APCD that uses water, which may include caustic additives or other chemicals, as

the sorbent. Wet scrubbers may use any of various design mechanisms to increase the contact between exhaust gases and the sorbent.

*Work practice standard* means any design, equipment, work practice, operational standard, or combination thereof, that is promulgated pursuant to section 112(h) of the Clean Air Act.

**Tables to Subpart KKKKK of Part 63**

As stated in § 63.8555, you must meet each emission limit in the following table that applies to you:

**TABLE 1 TO SUBPART KKKKK OF PART 63—EMISSION LIMITS**

For each . . .	You must meet the following emission limits . . .
1. Collection of all tunnel or roller kilns at facility.	HF and HCl emissions must not exceed 62 kilograms per hour (kg/hr) (140 pounds per hour (lb/hr)) HCl equivalent, under the health-based standard, as determined using Equations 4 and 5.
2. Existing floor tile roller kiln .....	a. PM emissions must not exceed 0.063 kilogram per megagram (kg/Mg) (0.13 pound per ton (lb/ton)) of fired product. b. Hg emissions must not exceed 6.3 E-05 kg/Mg (1.3 E-04 lb/ton) of fired product. c. Dioxin/furan emissions must not exceed 2.8 nanograms per kilogram (ng/kg) of fired product.
3. Existing wall tile roller kiln .....	a. PM emissions must not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product. b. Hg emissions must not exceed 1.1 E-04 kg/Mg (2.1 E-04 lb/ton) of fired product. c. Dioxin/furan emissions must not exceed 0.22 ng/kg of fired product.
4. Existing first-fire sanitaryware tunnel kiln.	a. PM emissions must not exceed 0.17 kg/Mg (0.34 lb/ton) of greenware fired. b. Hg emissions must not exceed 1.3 E-04 kg/Mg (2.6 E-04 lb/ton) of greenware fired. c. Dioxin/furan emissions must not exceed 3.3 ng/kg of greenware fired.
5. Existing tile glaze line with glaze spraying.	a. PM emissions must not exceed 0.93 kg/Mg (1.9 lb/ton) of first-fire glaze sprayed (dry weight basis). b. Hg emissions must not exceed 8.0 E-05 kg/Mg (1.6 E-04 lb/ton) of first-fire glaze sprayed (dry weight basis).
6. Existing sanitaryware manual glaze application.	PM emissions must not exceed 18 kg/Mg (35 lb/ton) of first-fire glaze sprayed (dry weight basis).
7. Existing sanitaryware spray machine glaze application.	PM emissions must not exceed 6.2 kg/Mg (13 lb/ton) of first-fire glaze sprayed (dry weight basis).
8. Existing sanitaryware robot glaze application.	PM emissions must not exceed 4.5 kg/Mg (8.9 lb/ton) of first-fire glaze sprayed (dry weight basis).
9. Existing floor tile spray dryer .....	Dioxin/furan emissions must not exceed 19 ng/kg of throughput processed.
10. Existing wall tile spray dryer .....	Dioxin/furan emissions must not exceed 0.058 ng/kg of throughput processed.
11. Existing floor tile press dryer .....	Dioxin/furan emissions must not exceed 0.024 ng/kg of throughput processed.
12. New or reconstructed floor tile roller kiln.	a. PM emissions must not exceed 0.019 kg/Mg (0.037 lb/ton) of fired product. b. Hg emissions must not exceed 2.0 E-05 kg/Mg (3.9 E-05 lb/ton) of fired product. c. Dioxin/furan emissions must not exceed 1.3 ng/kg of fired product.
13. New or reconstructed wall tile roller kiln.	a. PM emissions must not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product. b. Hg emissions must not exceed 1.1 E-04 kg/Mg (2.1 E-04 lb/ton) of fired product. c. Dioxin/furan emissions must not exceed 0.22 ng/kg of fired product.
14. New or reconstructed first-fire sanitaryware tunnel kiln.	a. PM emissions must not exceed 0.048 kg/Mg (0.095 lb/ton) of greenware fired. b. Hg emissions must not exceed 6.1 E-05 kg/Mg (1.3 E-04 lb/ton) of greenware fired. c. Dioxin/furan emissions must not exceed 0.99 ng/kg of greenware fired.
15. New or reconstructed tile glaze line with glaze spraying.	a. PM emissions must not exceed 0.31 kg/Mg (0.61 lb/ton) of first-fire glaze sprayed (dry weight basis). b. Hg emissions must not exceed 8.0 E-05 kg/Mg (1.6 E-04 lb/ton) of first-fire glaze sprayed (dry weight basis).
16. New or reconstructed sanitaryware manual glaze application.	PM emissions must not exceed 2.0 kg/Mg (3.9 lb/ton) of first-fire glaze sprayed (dry weight basis).
17. New or reconstructed sanitaryware spray machine glaze application.	PM emissions must not exceed 1.6 kg/Mg (3.2 lb/ton) of first-fire glaze sprayed (dry weight basis).
18. New or reconstructed sanitaryware robot glaze application.	PM emissions must not exceed 1.2 kg/Mg (2.3 lb/ton) of first-fire glaze sprayed (dry weight basis).
19. New or reconstructed floor tile spray dryer.	Dioxin/furan emissions must not exceed 0.071 ng/kg of throughput processed.
20. New or reconstructed wall tile spray dryer.	Dioxin/furan emissions must not exceed 0.058 ng/kg of throughput processed.
21. New or reconstructed floor tile press dryer.	Dioxin/furan emissions must not exceed 0.024 ng/kg of throughput processed.

As stated in § 63.8555, you must meet each operating limit in the following table that applies to you:

TABLE 2 TO SUBPART KKKKK OF PART 63—OPERATING LIMITS

For each . . .	You must . . .
1. Tunnel or roller kiln equipped with a DIFF or DLS/FF.	<ul style="list-style-type: none"> <li>a. If you use a bag leak detection system, initiate corrective action within 1 hour of a bag leak detection system alarm and complete corrective actions in accordance with your OM&amp;M plan; operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period; or maintain no VE from the DIFF or DLS/FF stack; and</li> <li>b. Maintain free-flowing lime in the feed hopper or silo and to the APCD at all times for continuous injection systems; maintain the feeder setting (on a per ton of throughput basis) at or above the level established during the performance test for continuous injection systems in which compliance was demonstrated.</li> </ul>
2. Tunnel or roller kiln equipped with a WS.	<ul style="list-style-type: none"> <li>a. Maintain the average scrubber liquid pH for each 3-hour block period at or above the average scrubber liquid pH established during the HF/HCl performance test in which compliance was demonstrated; and</li> <li>b. Maintain the average scrubber liquid flow rate for each 3-hour block period at or above the highest average scrubber liquid flow rate established during the HF/HCl and PM performance tests in which compliance was demonstrated.</li> </ul>
3. Tunnel or roller kiln equipped with an ACI system.	Maintain the average carbon flow rate for each 3-hour block period at or above the highest average carbon flow rate established during the Hg and dioxin/furan performance tests in which compliance was demonstrated.
4. Tunnel or roller kiln intending to comply with dioxin/furan emission limit without an ACI system.	If you intend to comply with the dioxin/furan emission limit without an ACI system, maintain the stack temperature at or below the highest 4-hour average stack temperature established during the dioxin/furan performance test in which compliance was demonstrated.
5. Tunnel or roller kiln with no add-on control.	<ul style="list-style-type: none"> <li>a. Maintain no VE from the stack; and</li> <li>b. Maintain the kiln process rate at or below the kiln process rate determined according to § 63.8595(g)(1) if your total facility maximum potential HCl-equivalent emissions are greater than the HCl-equivalent limit in Table 1 to this subpart; and</li> <li>c. Maintain the stack temperature at or below the highest 4-hour average stack temperature established during the dioxin/furan performance test in which compliance was demonstrated.</li> </ul>
6. Glaze spray operation equipped with a FF.	If you use a bag leak detection system, initiate corrective action within 1 hour of a bag leak detection system alarm and complete corrective actions in accordance with your OM&M plan; operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period; or maintain no VE from the FF stack; and
7. Glaze spray operation equipped with a WS.	<ul style="list-style-type: none"> <li>a. Maintain the average scrubber pressure drop for each 3-hour block period at or above the average pressure drop established during the PM performance test in which compliance was demonstrated; and</li> <li>b. Maintain the average scrubber liquid flow rate for each 3-hour block period at or above the average scrubber liquid flow rate established during the PM performance test in which compliance was demonstrated.</li> </ul>
8. Glaze spray operation equipped with a water curtain.	<p>Conduct daily inspections to verify the presence of water flow to the wet control system; and</p> <p>Conduct weekly visual inspections of the system ductwork and control equipment for leaks; and</p> <p>Conduct annual inspections of the interior of the control equipment (if applicable) to determine the structural integrity and condition of the control equipment.</p>
9. Glaze spray operation equipped with baffles.	Conduct an annual visual inspection of the baffles to confirm the baffles are in place.
10. Spray dryer .....	Maintain the average operating temperature for each 3-hour block period at or above the average temperature established during the dioxin/furan performance test in which compliance was demonstrated.
11. Floor tile press dryer .....	Maintain the average operating temperature for each 3-hour block period at or below the average temperature established during the dioxin/furan performance test in which compliance was demonstrated.

As stated in § 63.8555, you must comply with each work practice

standard in the following table that applies to you:

TABLE 3 TO SUBPART KKKKK OF PART 63—WORK PRACTICE STANDARDS

For each . . .	You must . . .	According to one of the following requirements . . .
1. Existing, new, or reconstructed sanitaryware shuttle kiln.	a. Minimize HAP emissions .....	<ul style="list-style-type: none"> <li>i. Use natural gas, or equivalent, as the kiln fuel, except during periods of natural gas curtailment or supply interruption, as defined in § 63.8665; and</li> <li>ii. Develop and use a designed firing time and temperature cycle for each sanitaryware shuttle kiln. You must either program the time and temperature cycle into your kiln or track each step on a log sheet; and</li> <li>iii. Label each sanitaryware shuttle kiln with the maximum load (in tons) of greenware that can be fired in the kiln during a single firing cycle; and</li> <li>iv. For each firing load, document the total tonnage of greenware placed in the kiln to ensure that it is not greater than the maximum load identified in item 1.a.iii; and</li> <li>v. Develop and follow maintenance procedures for each kiln that, at a minimum, specify the frequency of inspection and maintenance of temperature monitoring devices, controls that regulate air-to-fuel ratios, and controls that regulate firing cycles; and</li> </ul>

TABLE 3 TO SUBPART KKKKK OF PART 63—WORK PRACTICE STANDARDS—Continued

For each . . .	You must . . .	According to one of the following requirements . . .
2. Existing, new or reconstructed ceramic tile roller kiln, sanitaryware tunnel kiln, floor tile press dryer or ceramic tile spray dryer during periods of startup.	a. Minimize HAP emissions .....	vi. Develop and maintain records for each sanitaryware shuttle kiln, as specified in § 63.8640. i. Establish the startup production rate for each kiln or dryer; the minimum APCD inlet temperature for each APCD; and temperature profile for each kiln or dryer with no APCD and include them in your first compliance report, as specified in § 63.8635(c)(7); and ii. After initial loading of the kiln or dryer, remain at or below the startup production rate for the kiln or dryer until the kiln or dryer exhaust reaches the minimum APCD inlet temperature for a kiln or dryer with an APCD or until the kiln or dryer temperature profile is attained for a kiln or dryer with no APCD; and iii. If your kiln or dryer has an APCD, begin venting the exhaust from the kiln or dryer through the APCD by the time the kiln or dryer exhaust temperature reaches the minimum APCD inlet temperature.
3. Existing, new or reconstructed ceramic tile roller kiln, sanitaryware tunnel kiln, floor tile press dryer or ceramic tile spray dryer during periods of shutdown.	a. Minimize HAP emissions .....	i. Do not load the kiln or dryer once the kiln or dryer exhaust temperature falls below the minimum APCD inlet temperature if the kiln or dryer is controlled by an APCD or when the kiln or dryer temperature profile is no longer maintained for an uncontrolled kiln or dryer; and ii. If your kiln or dryer has an APCD, continue to vent the exhaust from the kiln or dryer through the APCD until the kiln or dryer exhaust temperature falls below the minimum inlet temperature for the APCD.
4. Existing, new or reconstructed ceramic tile roller kiln, sanitaryware tunnel kiln, floor tile press dryer or ceramic tile spray dryer during periods of routine control device maintenance.	a. Minimize HAP emissions .....	i. Develop and use a temperature profile for each kiln or dryer; and ii. Develop and follow maintenance procedures for each kiln that, at a minimum, specify the frequency of inspection and maintenance of temperature monitoring devices and controls that regulate air-to-fuel ratios; and  iii. Develop and maintain records for each kiln or dryer, as specified in § 63.8640(a)(3).

As stated in § 63.8595, you must conduct each performance test in the following table that applies to you:

TABLE 4 TO SUBPART KKKKK OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS

For each . . .	You must . . .	Using . . .	According to the following requirements . . .
1. Tunnel or roller kiln .....	a. Select locations of sampling ports and the number of traverse points. b. Determine velocities and volumetric flow rate.  c. Conduct gas molecular weight analysis.  d. Measure moisture content of the stack gas. e. Measure HF and HCl emissions.	Method 1 or 1A of 40 CFR part 60, appendix A-1.  Method 2 of 40 CFR part 60, appendix A-1.  Method 3 of 40 CFR part 60, appendix A-2.  Method 4 of 40 CFR part 60, appendix A-3. i. Method 26A of 40 CFR part 60, appendix A-8; or	Sampling sites must be located at the outlet of the APCD and prior to any releases to the atmosphere for all affected sources.  You may use Method 2A, 2C, 2D, or 2F of 40 CFR part 60, appendix A-1, or Method 2G of 40 CFR part 60, appendix A-2, as appropriate, as an alternative to using Method 2 of 40 CFR part 60, appendix A-1.  You may use Method 3A or 3B of 40 CFR part 60, appendix A-2, as appropriate, as an alternative to using Method 3 of 40 CFR part 60, appendix A-2. ANSI/ASME PTC 19.10-1981 (incorporated by reference, see § 63.14) may be used as an alternative to the manual procedures (but not the instrumental procedures) in Methods 3A and 3B.  You may use Method 26 of 40 CFR part 60, appendix A-8, as an alternative to using Method 26A of 40 CFR part 60, appendix A-8, when no acid PM (e.g., HF or HCl dissolved in water droplets emitted by sources controlled by a WS) is present. ASTM D6735-01 (Reapproved 2009) (incorporated by reference, see § 63.14) may be used as an alternative to Methods 26 and 26A.

TABLE 4 TO SUBPART KKKKK OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS—Continued

For each . . .	You must . . .	Using . . .	According to the following requirements . . .
		ii. Method 320 of appendix A of this part.	When using Method 320 of appendix A of this part, you must follow the analyte spiking procedures of section 13 of Method 320 of appendix A of this part, unless you can demonstrate that the complete spiking procedure has been conducted at a similar source. ASTM D6348–03 (Reapproved 2010) (incorporated by reference, see §63.14) may be used as an alternative to Method 320 if the test plan preparation and implementation in Annexes A1–A8 are mandatory and the %R in Annex A5 is determined for each target analyte.
	f. Measure PM emissions ..	i. Method 5 of 40 CFR part 60, appendix A–3; or.	
	g. Measure Hg emissions	ii. Method 29 of 40 CFR part 60, appendix A–8. Method 29 of 40 CFR part 60, appendix A–8.	ASTM D6784–02 (Reapproved 2008) (incorporated by reference, see §63.14) may be used as an alternative to Method 29 (portion for Hg only).
	h. Measure dioxin/furan emissions.	Method 23 of 40 CFR part 60, appendix A–7.	
2. Glaze spray operation .....	a. Select locations of sampling ports and the number of traverse points.	Method 1 or 1A of 40 CFR part 60, appendix A–1.	Sampling sites must be located at the outlet of the APCD and prior to any releases to the atmosphere for all affected sources.
	b. Determine velocities and volumetric flow rate.	Method 2 of 40 CFR part 60, appendix A–1.	You may use Method 2A, 2C, 2D, or 2F of 40 CFR part 60, appendix A–1, or Method 2G of 40 CFR part 60, appendix A–2, as appropriate, as an alternative to using Method 2 of 40 CFR part 60, appendix A–1.
	c. Conduct gas molecular weight analysis.	Method 3 of 40 CFR part 60, appendix A–2.	You may use Method 3A or 3B of 40 CFR part 60, appendix A–2, as appropriate, as an alternative to using Method 3 of 40 CFR part 60, appendix A–2. ANSI/ASME PTC 19.10–1981 (incorporated by reference, see §63.14) may be used as an alternative to the manual procedures (but not the instrumental procedures) in Methods 3A and 3B.
	d. Measure moisture content of the stack gas.	Method 4 of 40 CFR part 60, appendix A–3.	
	e. Measure PM emissions	Method 5 of 40 CFR part 60, appendix A–3.	
	f. Measure Hg emissions (tile glaze spray operations only).	Method 29 of 40 CFR part 60, appendix A–8.	ASTM D6784–02 (Reapproved 2008) (incorporated by reference, see §63.14) may be used as an alternative to Method 29 (portion for Hg only).
3. Spray dryer or floor tile press dryer.	a. Select locations of sampling ports and the number of traverse points.	Method 1 or 1A of 40 CFR part 60, appendix A–1.	Sampling sites must be located at the outlet of the APCD and prior to any releases to the atmosphere for all affected sources.
	b. Determine velocities and volumetric flow rate.	Method 2 of 40 CFR part 60, appendix A–1.	You may use Method 2A, 2C, 2D, or 2F of 40 CFR part 60, appendix A–1, or Method 2G of 40 CFR part 60, appendix A–2, as appropriate, as an alternative to using Method 2 of 40 CFR part 60, appendix A–1.
	c. Conduct gas molecular weight analysis.	Method 3 of 40 CFR part 60, appendix A–2.	You may use Method 3A or 3B of 40 CFR part 60, appendix A–2, as appropriate, as an alternative to using Method 3 of 40 CFR part 60, appendix A–2. ANSI/ASME PTC 19.10–1981 (incorporated by reference, see §63.14) may be used as an alternative to the manual procedures (but not the instrumental procedures) in Methods 3A and 3B.
	d. Measure moisture content of the stack gas.	Method 4 of 40 CFR part 60, appendix A–3.	
	e. Measure dioxin/furan emissions.	Method 23 of 40 CFR part 60, appendix A–7.	
4. Tunnel or roller kiln with no add-on control.	a. Establish the operating limit(s) for kiln process rate if the total facility maximum potential HCl-equivalent emissions are greater than the HCl-equivalent limit in Table 1 to this subpart.	HCl-equivalent limit in Table 1 to this subpart and emissions and production data from the HF/HCl/Cl <sub>2</sub> performance test.	Using the procedures in §63.8595(g)(1), you must determine the maximum process rate(s) for your kiln(s) that would ensure total facility maximum potential HCl-equivalent emissions remain at or below the HCl-equivalent limit in Table 1 to this subpart. The maximum process rate(s) would become your site-specific process rate operating limit(s).

TABLE 4 TO SUBPART KKKKK OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS—Continued

For each . . .	You must . . .	Using . . .	According to the following requirements . . .
5. Tunnel or roller kiln that is complying with PM and/or Hg production-based emission limits.	b. Establish the stack temperature operating limit.  Determine the production rate during each PM/Hg test run in order to determine compliance with PM and/or Hg production-based emission limits.	Data from the temperature measurement device during the dioxin/furan performance test.  Production data collected during the PM/Hg performance tests (e.g., the number of ceramic pieces and weight per piece in the kiln during a test run divided by the amount of time to fire a piece).	You must continuously measure the stack temperature and determine and record the temperature values for the three test runs. The highest 4-hour average stack temperature of the three test runs establishes your maximum site-specific stack temperature operating limit.  You must measure and record the production rate, on a ton of throughput processed basis, of the affected kiln for each of the three test runs.
6. Tunnel or roller kiln equipped with a DIFF or DLS/FF.	Establish the operating limit for the lime feeder setting.	Data from the lime feeder during the HF/HCl performance test.	For continuous lime injection systems, you must ensure that lime in the feed hopper or silo and to the APCD is free-flowing at all times during the performance test and record the feeder setting, on a per ton of throughput basis, for the three test runs. If the feed rate setting varies during the three test runs, determine and record the average feed rate from the three test runs. The average of the three test runs establishes your minimum site-specific feed rate operating limit.
7. Tunnel or roller kiln equipped with a WS.	a. Establish the operating limit for the average scrubber liquid pH.  b. Establish the operating limit for the average scrubber liquid flow rate.	Data from the pH measurement device during the HF/HCl performance test.  Data from the flow rate measurement device during the HF/HCl and PM performance tests.	You must continuously measure the scrubber liquid pH, determine and record the block average pH values for the three test runs, and determine and record the 3-hour block average of the recorded pH measurements for the three test runs. The average of the three test runs establishes your minimum site-specific liquid pH operating limit.  You must continuously measure the scrubber liquid flow rate, determine and record the block average flow rate values for the three test runs, and determine and record the 3-hour block average of the recorded flow rate measurements for the three test runs. The average of the three test runs establishes your minimum site-specific liquid flow rate operating level. If different average wet scrubber liquid flow rate values are measured during the HF/HCl and PM tests, the highest of the average values become your site-specific operating limit.
8. Tunnel or roller kiln equipped with an ACI system.	Establish the operating limit for the average carbon flow rate.	Data from the carbon flow rate measurement conducted during the Hg performance test.	You must measure the carbon flow rate during each test run, determine and record the block average carbon flow rate values for the three test runs, and determine and record the 3-hour block average of the recorded carbon flow rate measurements for the three test runs. The average of the three test runs establishes your minimum site-specific activated carbon flow rate operating limit.
9. Tunnel or roller kiln intending to comply with dioxin/furan emission limit without an ACI system.	Establish the stack temperature operating limit.	Data from the temperature measurement device during the dioxin/furan performance test.	You must continuously measure the stack temperature and determine and record the temperature values for the three test runs. The highest 4-hour average stack temperature of the three test runs establishes your maximum site-specific stack temperature operating limit.
10. Glaze spray operation equipped with a WS.	a. Establish the operating limit for the average scrubber pressure drop.	Data from the pressure drop measurement device during the PM performance test.	You must continuously measure the scrubber pressure drop, determine and record the block average pressure drop values for the three test runs, and determine and record the 3-hour block average of the recorded pressure drop measurements for the three test runs. The average of the three test runs establishes your minimum site-specific pressure drop operating limit.

TABLE 4 TO SUBPART KKKKK OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS—Continued

For each . . .	You must . . .	Using . . .	According to the following requirements . . .
	b. Establish the operating limit for the average scrubber liquid flow rate.	Data from the flow rate measurement device during the PM performance test.	You must continuously measure the scrubber liquid flow rate, determine and record the block average flow rate values for the three test runs, and determine and record the 3-hour block average of the recorded flow rate measurements for the three test runs. The average of the three test runs establishes your minimum site-specific liquid flow rate operating limit.
11. Spray dryer .....	Establish the operating limit for operating temperature.	Data from the temperature measurement device during the dioxin/furan performance test.	You must continuously measure the operating temperature, determine and record the block average temperature values for the three test runs, and determine and record the 3-hour block average of the recorded temperature measurements for the three test runs. The average of the three test runs establishes your minimum site-specific operating limit.
12. Floor tile press dryer .....	Establish the operating limit for operating temperature.	Data from the temperature measurement device during the dioxin/furan performance test.	You must continuously measure the operating temperature, determine and record the block average temperature values for the three test runs, and determine and record the 3-hour block average of the recorded temperature measurements for the three test runs. The average of the three test runs establishes your maximum site-specific operating limit.

As stated in § 63.8595(f)(3), you must demonstrate initial compliance with each dioxin/furan emission limit that applies to you by calculating the sum of the 2,3,7,8-TCDD TEQs using the TEFs in the following table:

TABLE 5 TO SUBPART KKKKK OF PART 63—TOXIC EQUIVALENCY FACTORS

For each dioxin/furan congener . . .	You must calculate its 2,3,7,8-TCDD TEQ using the following TEF . . .
2,3,7,8-tetrachlorodibenzo-p-dioxin .....	1
1,2,3,7,8-pentachlorodibenzo-p-dioxin .....	1
1,2,3,4,7,8-hexachlorodibenzo-p-dioxin .....	0.1
1,2,3,7,8,9-hexachlorodibenzo-p-dioxin .....	0.1
1,2,3,6,7,8-hexachlorodibenzo-p-dioxin .....	0.1
1,2,3,4,6,7,8-heptachlorodibenzo-p-dioxin .....	0.01
Octachlorodibenzo-p-dioxin .....	0.0003
2,3,7,8-tetrachlorodibenzofuran .....	0.1
1,2,3,7,8-pentachlorodibenzofuran .....	0.03
2,3,4,7,8-pentachlorodibenzofuran .....	0.3
1,2,3,4,7,8-hexachlorodibenzofuran .....	0.1
1,2,3,6,7,8-hexachlorodibenzofuran .....	0.1
1,2,3,7,8,9-hexachlorodibenzofuran .....	0.1
2,3,4,6,7,8-hexachlorodibenzofuran .....	0.1
1,2,3,4,6,7,8-heptachlorodibenzofuran .....	0.01
1,2,3,4,7,8,9-heptachlorodibenzofuran .....	0.01
Octachlorodibenzofuran .....	0.0003

As stated in § 63.8605, you must demonstrate initial compliance with each emission limitation and work practice standard that applies to you according to the following table:

TABLE 6 TO SUBPART KKKKK OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS

For each . . .	For the following . . .	You have demonstrated initial compliance if . . .
1. Collection of all tunnel or roller kilns at the facility.	a. HF, HCl, and Cl <sub>2</sub> emissions must not exceed 62 kg/hr (140 lb/hr) HCl equivalent.	i. You measure HF and HCl emissions for each kiln using Method 26 or 26A of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6735-01 (Reapproved 2009) (incorporated by reference, see § 63.14); or Method 320 of appendix A of this part or its alternative, ASTM D6348-03 (Reapproved 2010) (incorporated by reference, see § 63.14); and



TABLE 6 TO SUBPART KKKKK OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You have demonstrated initial compliance if . . .
2. Existing floor tile roller kiln .....	<p>a. PM emissions must not exceed 0.063 kg/Mg (0.13 lb/ton) of fired product.</p> <p>b. Hg emissions must not exceed 6.3 E-05 kg/Mg (1.3 E-04 lb/ton) of fired product.</p> <p>c. Dioxin/furan emissions must not exceed 2.8 ng/kg of fired product.</p>	<p>ii. You calculate the HCl-equivalent emissions for HF for each kiln using Equation 4 to this subpart; and</p> <p>iii. You sum the HCl-equivalent values for all kilns at the facility using Equation 5 to this subpart; and</p> <p>iv. The facility total HCl-equivalent does not exceed 62 kg/hr (140 lb/hr).</p> <p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3 or Method 29 of 40 CFR part 60, appendix A-8, over the period of the initial performance test, according to the calculations in § 63.8595(f)(1), do not exceed 0.063 kg/Mg (0.13 lb/ton) of fired product; and</p> <p>ii. You establish and have a record of the applicable operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.063 kg/Mg (0.13 lb/ton) of fired product.</p> <p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6784-02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 6.3 E-05 kg/Mg (1.3 E-04 lb/ton) of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 6.3 E-05 kg/Mg (1.3 E-04 lb/ton) of fired product.</p> <p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 2.8 ng/kg of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 2.8 ng/kg of fired product.</p>
3. Existing wall tile roller kiln .....	<p>a. PM emissions must not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product.</p> <p>b. Hg emissions must not exceed 1.1 E-04 kg/Mg (2.1 E-04 lb/ton) of fired product.</p> <p>c. Dioxin/furan emissions must not exceed 0.22 ng/kg of fired product.</p>	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3 or Method 29 of 40 CFR part 60, appendix A-8, over the period of the initial performance test, according to the calculations in § 63.8595(f)(1), do not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product.</p> <p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6784-02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 1.1 E-04 kg/Mg (2.1 E-04 lb/ton) of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 1.1 E-04 kg/Mg (2.1 E-04 lb/ton) of fired product.</p> <p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 0.22 ng/kg of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 0.22 ng/kg of fired product.</p>
4. Existing first-fire sanitaryware tunnel kiln.	<p>a. PM emissions must not exceed 0.17 kg/Mg (0.34 lb/ton) of greenware fired.</p> <p>b. Hg emissions must not exceed 1.3 E-04 kg/Mg (2.6 E-04 lb/ton) of greenware fired.</p>	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3 or Method 29 of 40 CFR part 60, appendix A-8, over the period of the initial performance test, according to the calculations in § 63.8595(f)(1), do not exceed 0.17 kg/Mg (0.34 lb/ton) of greenware fired; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.17 kg/Mg (0.34 lb/ton) of greenware fired.</p> <p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6784-02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 1.3 E-04 kg/Mg (2.6 E-04 lb/ton) of greenware fired; and</p>

TABLE 6 TO SUBPART KKKKK OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You have demonstrated initial compliance if . . .
5. Existing tile glaze line with glaze spraying.	<p>c. Dioxin/furan emissions must not exceed 3.3 ng/kg of greenware fired.</p> <p>a. PM emissions must not exceed 0.93 kg/Mg (1.9 lb/ton) of first-fire glaze sprayed (dry weight basis).</p> <p>b. Hg emissions must not exceed 8.0 E-05 kg/Mg (1.6 E-04 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>	<p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 1.3 E-04 kg/Mg (2.6 E-04 lb/ton) of greenware fired.</p> <p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 3.3 ng/kg of greenware fired; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 3.3 ng/kg of greenware fired.</p> <p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3, over the period of the initial performance test, according to the calculations in § 63.8595(f)(2), do not exceed 0.93 kg/Mg (1.9 lb/ton) of first-fire glaze sprayed (dry weight basis); and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.93 kg/Mg (1.9 lb/ton) of first-fire glaze sprayed (dry weight basis).</p> <p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6784-02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 8.0 E-05 kg/Mg (1.6 E-04 lb/ton) of first-fire glaze sprayed (dry weight basis); and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 8.0 E-05 kg/Mg (1.6 E-04 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>
6. Existing sanitaryware manual glaze application.	a. PM emissions must not exceed 18 kg/Mg (35 lb/ton) of first-fire glaze sprayed (dry weight basis).	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3, over the period of the initial performance test, according to the calculations in § 63.8595(f)(2), do not exceed 18 kg/Mg (35 lb/ton) of first-fire glaze sprayed (dry weight basis); and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 18 kg/Mg (35 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>
7. Existing sanitaryware spray machine glaze application.	a. PM emissions must not exceed 6.2 kg/Mg (13 lb/ton) of first-fire glaze sprayed (dry weight basis).	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3, over the period of the initial performance test, according to the calculations in § 63.8595(f)(2), do not exceed 6.2 kg/Mg (13 lb/ton) of first-fire glaze sprayed (dry weight basis); and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 6.2 kg/Mg (13 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>
8. Existing sanitaryware robot glaze application.	a. PM emissions must not exceed 4.5 kg/Mg (8.9 lb/ton) of first-fire glaze sprayed (dry weight basis).	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3, over the period of the initial performance test, according to the calculations in § 63.8595(f)(2), do not exceed 4.5 kg/Mg (8.9 lb/ton) of first-fire glaze sprayed (dry weight basis); and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 4.5 kg/Mg (8.9 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>
9. Existing floor tile spray dryer .....	a. Dioxin/furan emissions must not exceed 19 ng/kg of throughput processed.	<p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 19 ng/kg of throughput processed; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 19 ng/kg of throughput processed.</p>
10. Existing wall tile spray dryer .....	a. Dioxin/furan emissions must not exceed 0.058 ng/kg of throughput processed.	<p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 0.058 ng/kg of throughput processed; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 0.058 ng/kg of throughput processed.</p>
11. Existing floor tile press dryer .....	a. Dioxin/furan emissions must not exceed 0.024 ng/kg of throughput processed.	i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 0.024 ng/kg of throughput processed; and

TABLE 6 TO SUBPART KKKKK OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You have demonstrated initial compliance if . . .
12. New or reconstructed floor tile roller kiln.	<p>a. PM emissions must not exceed 0.019 kg/Mg (0.037 lb/ton) of fired product.</p> <p>b. Hg emissions must not exceed 2.0 E-05 kg/Mg (3.9 E-05 lb/ton) of fired product.</p> <p>c. Dioxin/furan emissions must not exceed 1.3 ng/kg of fired product.</p>	<p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 0.024 ng/kg of throughput processed.</p> <p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3 or Method 29 of 40 CFR part 60, appendix A-8, over the period of the initial performance test, according to the calculations in § 63.8595(f)(1), do not exceed 0.019 kg/Mg (0.037 lb/ton) of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.019 kg/Mg (0.037 lb/ton) of fired product.</p> <p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6784-02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 2.0 E-05 kg/Mg (3.9 E-05 lb/ton) of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 2.0 E-05 kg/Mg (3.9 E-05 lb/ton) of fired product.</p> <p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 1.3 ng/kg of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 1.3 ng/kg of fired product.</p>
13. New or reconstructed wall tile roller kiln.	<p>a. PM emissions must not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product.</p> <p>b. Hg emissions must not exceed 1.1 E-04 kg/Mg (2.1 E-04 lb/ton) of fired product.</p> <p>c. Dioxin/furan emissions must not exceed 0.22 ng/kg of fired product.</p>	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3 or Method 29 of 40 CFR part 60, appendix A-8, over the period of the initial performance test, according to the calculations in § 63.8595(f)(1), do not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.19 kg/Mg (0.37 lb/ton) of fired product.</p> <p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6784-02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 1.1 E-04 kg/Mg (2.1 E-04 lb/ton) of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 1.1 E-04 kg/Mg (2.1 E-04 lb/ton) of fired product.</p> <p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 0.22 ng/kg of fired product; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 0.22 ng/kg of fired product.</p>
14. New or reconstructed first-fire sanitaryware tunnel kiln.	<p>a. PM emissions must not exceed 0.048 kg/Mg (0.095 lb/ton) of greenware fired.</p> <p>b. Hg emissions must not exceed 6.1 E-05 kg/Mg (1.3 E-04 lb/ton) of greenware fired.</p>	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3 or Method 29 of 40 CFR part 60, appendix A-8, over the period of the initial performance test, according to the calculations in § 63.8595(f)(1), do not exceed 0.048 kg/Mg (0.095 lb/ton) of greenware fired; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.048 kg/Mg (0.095 lb/ton) of greenware fired.</p> <p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6784-02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 6.1 E-05 kg/Mg (1.3 E-04 lb/ton) of greenware fired; and</p>

TABLE 6 TO SUBPART KKKKK OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You have demonstrated initial compliance if . . .
15. New or reconstructed tile glaze line with glaze spraying.	<p>c. Dioxin/furan emissions must not exceed 0.99 ng/kg of greenware fired.</p> <p>a. PM emissions must not exceed 0.31 kg/Mg (0.61 lb/ton) of first-fire glaze sprayed (dry weight basis).</p> <p>b. Hg emissions must not exceed 8.0 E-05 kg/Mg (1.6 E-04 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>	<p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 6.1 E-05 kg/Mg (1.3 E-04 lb/ton) of greenware fired.</p> <p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 0.99 ng/kg of greenware fired; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 0.99 ng/kg of greenware fired.</p> <p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3, over the period of the initial performance test, according to the calculations in § 63.8595(f)(2), do not exceed 0.31 kg/Mg (0.61 lb/ton) of first-fire glaze sprayed (dry weight basis); and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 0.31 kg/Mg (0.61 lb/ton) of first-fire glaze sprayed (dry weight basis).</p> <p>i. The Hg emissions measured using Method 29 of 40 CFR part 60, appendix A-8 or its alternative, ASTM D6784-02 (Reapproved 2008) (incorporated by reference, see § 63.14), over the period of the initial performance test, do not exceed 8.0 E-05 kg/Mg (1.6 E-04 lb/ton) of first-fire glaze sprayed (dry weight basis); and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which Hg emissions did not exceed 8.0 E-05 kg/Mg (1.6 E-04 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>
16. New or reconstructed sanitaryware manual glaze application.	<p>a. PM emissions must not exceed 2.0 kg/Mg (3.9 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3, over the period of the initial performance test, according to the calculations in § 63.8595(f)(2), do not exceed 2.0 kg/Mg (3.9 lb/ton) of first-fire glaze sprayed (dry weight basis); and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 2.0 kg/Mg (3.9 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>
17. New or reconstructed sanitaryware spray machine glaze application.	<p>a. PM emissions must not exceed 1.6 kg/Mg (3.2 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3, over the period of the initial performance test, according to the calculations in § 63.8595(f)(2), do not exceed 1.6 kg/Mg (3.2 lb/ton) of first-fire glaze sprayed (dry weight basis); and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 1.6 kg/Mg (3.2 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>
18. New or reconstructed sanitaryware robot glaze application.	<p>a. PM emissions must not exceed 1.2 kg/Mg (2.3 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>	<p>i. The PM emissions measured using Method 5 of 40 CFR part 60, appendix A-3, over the period of the initial performance test, according to the calculations in § 63.8595(f)(2), do not exceed 1.2 kg/Mg (2.3 lb/ton) of first-fire glaze sprayed (dry weight basis); and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which PM emissions did not exceed 1.2 kg/Mg (2.3 lb/ton) of first-fire glaze sprayed (dry weight basis).</p>
19. New or reconstructed floor tile spray dryer.	<p>a. Dioxin/furan emissions must not exceed 0.071 ng/kg of throughput processed.</p>	<p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 0.071 ng/kg of throughput processed; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 0.071 ng/kg of throughput processed.</p>
20. New or reconstructed wall tile spray dryer.	<p>a. Dioxin/furan emissions must not exceed 0.058 ng/kg of throughput processed.</p>	<p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 0.058 ng/kg of throughput processed; and</p> <p>ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 0.058 ng/kg of throughput processed.</p>
21. New or reconstructed floor tile press dryer.	<p>a. Dioxin/furan emissions must not exceed 0.024 ng/kg of throughput processed.</p>	<p>i. The dioxin/furan emissions measured using Method 23 of 40 CFR part 60, appendix A-7, over the period of the initial performance test, do not exceed 0.024 ng/kg of throughput processed; and</p>

TABLE 6 TO SUBPART KKKKK OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You have demonstrated initial compliance if . . .
22. Existing, new, or reconstructed sanitaryware shuttle kiln.	a. Minimize HAP emissions .....	ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the 3-hour performance test during which dioxin/furan emissions did not exceed 0.024 ng/kg of throughput processed. i. Use natural gas, or equivalent, as the kiln fuel; and  ii. Develop a designed firing time and temperature cycle for the sanitaryware shuttle kiln. You must either program the time and temperature cycle into your kiln or track each step on a log sheet; and iii. Label each sanitaryware shuttle kiln with the maximum load (in tons) of greenware that can be fired in the kiln during a single firing cycle; and iv. Develop maintenance procedures for each kiln that, at a minimum, specify the frequency of inspection and maintenance of temperature monitoring devices, controls that regulate air-to-fuel ratios, and controls that regulate firing cycles.

As stated in § 63.8620, you must demonstrate continuous compliance with each emission limitation and work practice standard that applies to you according to the following table:

TABLE 7 TO SUBPART KKKKK OF PART 63—CONTINUOUS COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS

For each . . .	For the following . . .	You must demonstrate continuous compliance by . . .
1. Tunnel or roller kiln equipped with a DIFF or DLS/FF.	a. Each emission limit in Table 1 to this subpart and each operating limit in Item 1 of Table 2 to this subpart for kilns equipped with DIFF or DLS/FF.	i. If you use a bag leak detection system, as prescribed in 63.8450(e), initiating corrective action within 1 hour of a bag leak detection system alarm and completing corrective actions in accordance with your OM&M plan; operating and maintaining the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period; in calculating this operating time fraction, if inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted; if corrective action is required, each alarm is counted as a minimum of 1 hour; if you take longer than 1 hour to initiate corrective action, the alarm time is counted as the actual amount of time taken by you to initiate corrective action; or performing VE observations of the DIFF or DLS/FF stack at the frequency specified in § 63.8620(e) using Method 22 of 40 CFR part 60, appendix A-7; and maintaining no VE from the DIFF or DLS/FF stack; and ii. Verifying that lime is free-flowing via a load cell, carrier gas/lime flow indicator, carrier gas pressure drop measurement system, or other system; recording all monitor or sensor output, and if lime is found not to be free flowing, promptly initiating and completing corrective actions in accordance with your OM&M plan; recording the feeder setting once each shift of operation to verify that the feeder setting is being maintained at or above the level established during the HF/HCl performance test in which compliance was demonstrated.
2. Tunnel or roller kiln equipped with a WS.	a. Each emission limit in Table 1 to this subpart and each operating limit in Item 2 of Table 2 to this subpart for kilns equipped with WS.	i. Collecting the scrubber liquid pH data according to § 63.8600(a); reducing the scrubber liquid pH data to 3-hour block averages according to § 63.8600(a); maintaining the average scrubber liquid pH for each 3-hour block period at or above the average scrubber liquid pH established during the HF/HCl performance test in which compliance was demonstrated; and ii. Collecting the scrubber liquid flow rate data according to § 63.8600(a); reducing the scrubber liquid flow rate data to 3-hour block averages according to § 63.8600(a); maintaining the average scrubber liquid flow rate for each 3-hour block period at or above the highest average scrubber liquid flow rate established during the HF/HCl and PM performance tests in which compliance was demonstrated.

TABLE 7 TO SUBPART KKKKK OF PART 63—CONTINUOUS COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You must demonstrate continuous compliance by . . .
3. Tunnel or roller kiln equipped with an ACI system.	Each emission limit in Table 1 to this subpart and each operating limit in Item 3 of Table 2 to this subpart for kilns equipped with ACI system.	Collecting the carbon flow rate data according to § 63.8600(a); reducing the carbon flow rate data to 3-hour block averages according to § 63.8600(a); maintaining the average carbon flow rate for each 3-hour block period at or above the highest average carbon flow rate established during the Hg and dioxin/furan performance tests in which compliance was demonstrated.
4. Tunnel or roller kiln intending to comply with dioxin/furan emission limit without an ACI system.	Each emission limit in Table 1 to this subpart and each operating limit in Item 4 of Table 2 to this subpart for kilns intending to comply with dioxin/furan emission limit without an ACI system.	Collecting the stack temperature data according to § 63.8600(a); and maintaining the stack temperature at or below the highest stack temperature established during the dioxin/furan performance test in which compliance was demonstrated.
5. Tunnel or roller kiln with no add-on control.	a. Each emission limit in Table 1 to this subpart and each operating limit in Item 5 of Table 2 to this subpart for tunnel or roller kilns with no add-on control.	<ul style="list-style-type: none"> <li>i. Performing VE observations of the stack at the frequency specified in § 63.8620(e) using Method 22 of 40 CFR part 60, appendix A–7; and maintaining no VE from the stack.</li> <li>ii. If your last calculated total facility maximum potential HCl-equivalent was not at or below the health-based standard in Table 1 to this subpart, collecting the kiln process rate data according to § 63.8600(a); reducing the kiln process rate data to 3-hour block averages according to § 63.8600(a); maintaining the average kiln process rate for each 3-hour block period at or below the kiln process rate determined according to § 63.8595(g)(1).</li> <li>iii. Collecting the stack temperature data according to § 63.8600(a); and maintaining the stack temperature at or below the highest stack temperature established during the dioxin/furan performance test in which compliance was demonstrated.</li> </ul>
6. Glaze spray operation equipped with a FF.	Each emission limit in Table 1 to this subpart and each operating limit in Item 6 of Table 2 to this subpart for glaze spray operations equipped with a FF.	If you use a bag leak detection system, initiating corrective action within 1 hour of a bag leak detection system alarm and completing corrective actions in accordance with your OM&M plan; operating and maintaining the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period; in calculating this operating time fraction, if inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted; if corrective action is required, each alarm is counted as a minimum of 1 hour; if you take longer than 1 hour to initiate corrective action, the alarm time is counted as the actual amount of time taken by you to initiate corrective action; or performing VE observations of the FF stack at the frequency specified in § 63.8620(e) using Method 22 of 40 CFR part 60, appendix A–7; and maintaining no VE from the FF stack.
7. Glaze spray operation equipped with a WS.	a. Each emission limit in Table 1 to this subpart and each operating limit in Item 7 of Table 2 to this subpart for kilns equipped with WS.	<ul style="list-style-type: none"> <li>i. Collecting the scrubber pressure drop data according to § 63.8600(a); reducing the scrubber pressure drop data to 3-hour block averages according to § 63.8600(a); maintaining the average scrubber pressure drop for each 3-hour block period at or above the average pressure drop established during the PM performance test in which compliance was demonstrated; and</li> <li>ii. Collecting the scrubber liquid flow rate data according to § 63.8600(a); reducing the scrubber liquid flow rate data to 3-hour block averages according to § 63.8600(a); maintaining the average scrubber liquid flow rate for each 3-hour block period at or above the average scrubber liquid flow rate established during the PM performance test in which compliance was demonstrated.</li> </ul>
8. Glaze spray operation equipped with a water curtain.	a. Each emission limit in Table 1 to this subpart and each operating limit in Item 8 of Table 2 to this subpart for kilns equipped with a water curtain.	<ul style="list-style-type: none"> <li>i. Conducting daily inspections to verify the presence of water flow to the wet control system; and</li> <li>ii. Conducting weekly visual inspections of the system ductwork and control equipment for leaks; and</li> <li>iii. Conducting annual inspections of the interior of the control equipment (if applicable) to determine the structural integrity and condition of the control equipment.</li> </ul>
9. Glaze spray operation equipped with baffles.	Each emission limit in Table 1 to this subpart and each operating limit in Item 9 of Table 2 to this subpart for kilns equipped with baffles.	Conducting an annual visual inspection of the baffles to confirm the baffles are in place.
10. Spray dryer .....	Each emission limit in Table 1 to this subpart and each operating limit in Item 10 of Table 2 to this subpart for spray dryers.	Collecting the operating temperature data according to § 63.8600(a); reducing the operating temperature data to 3-hour block averages according to § 63.8600(a); maintaining the average operating temperature for each 3-hour block period at or above the average operating temperature established during the dioxin/furan performance test in which compliance was demonstrated.

TABLE 7 TO SUBPART KKKKK OF PART 63—CONTINUOUS COMPLIANCE WITH EMISSION LIMITATIONS AND WORK PRACTICE STANDARDS—Continued

For each . . .	For the following . . .	You must demonstrate continuous compliance by . . .
11. Floor tile press dryer .....	Each emission limit in Table 1 to this subpart and each operating limit in Item 11 of Table 2 to this subpart for floor tile press dryers..	Collecting the operating temperature data according to § 63.8600(a); reducing the operating temperature data to 3-hour block averages according to § 63.8600(a); maintaining the average operating temperature for each 3-hour block period at or below the average operating temperature established during the dioxin/furan performance test in which compliance was demonstrated.
12. Sanitaryware shuttle kiln .....	a. Minimize HAP emissions .....	i. Maintaining records documenting your use of natural gas, or an equivalent fuel, as the kiln fuel at all times except during periods of natural gas curtailment or supply interruption; and ii. If you intend to use an alternative fuel, submitting a notification of alternative fuel use within 48 hours of the declaration of a period of natural gas curtailment or supply interruption, as defined in § 63.8665; and iii. Submitting a report of alternative fuel use within 10 working days after terminating the use of the alternative fuel, as specified in § 63.8635(g); and iv. Using a designed firing time and temperature cycle for each sanitaryware shuttle kiln; and v. For each firing load, documenting the total tonnage of greenware placed in the kiln to ensure that it is not greater than the maximum load identified in Item 1.a.iii of Table 3 to this subpart; and vi. Following maintenance procedures for each kiln that, at a minimum, specify the frequency of inspection and maintenance of temperature monitoring devices, controls that regulate air-to-fuel ratios, and controls that regulate firing cycles; and vii. Developing and maintaining records for each sanitaryware shuttle kiln, as specified in § 63.8640.

As stated in § 63.8545, you must meet each compliance date in the following table that applies to you:

TABLE 8 TO SUBPART KKKKK OF PART 63—COMPLIANCE DATES

If you have a(n) . . .	Then you must . . .	No later than . . .
1. New or reconstructed affected source and the initial startup of your affected source is after December 18, 2014, but before December 28, 2015.	Comply with the applicable emission limitations and work practice standards in Tables 1, 2, and 3 to this subpart.	December 28, 2015.
2. New or reconstructed affected source and the initial startup of your affected source is after December 28, 2015.	Comply with the applicable emission limitations and work practice standards in Tables 1, 2, and 3 to this subpart.	Initial startup of your affected source.
3. Existing affected source .....	Comply with the applicable emission limitations and work practice standards in Tables 1, 2, and 3 to this subpart.	December 26, 2018.
4. Existing area source that increases its emissions or its potential to emit such that it becomes a major source of HAP by adding a new affected source or by reconstructing.	Be in compliance with this subpart .....	Initial startup of your affected source as a major source.
5. New area source ( <i>i.e.</i> , an area source for which construction or reconstruction commenced after December 18, 2014) that increases its emissions or its potential to emit such that it becomes a major source of HAP.	Be in compliance with this subpart .....	Initial startup of your affected source as a major source.

As stated in § 63.8630, you must submit each notification that applies to you according to the following table:

TABLE 9 TO SUBPART KKKKK OF PART 63—DEADLINES FOR SUBMITTING NOTIFICATIONS

If you . . .	You must . . .	No later than . . .	As specified in . . .
1. Start up your affected source before December 28, 2015.	Submit an Initial Notification .....	June 22, 2016 .....	§ 63.9(b)(2).

TABLE 9 TO SUBPART KKKKK OF PART 63—DEADLINES FOR SUBMITTING NOTIFICATIONS—Continued

If you . . .	You must . . .	No later than . . .	As specified in . . .
2. Start up your new or reconstructed affected source on or after December 28, 2015.	Submit an Initial Notification .....	120 calendar days after you become subject to this subpart.	§ 63.9(b)(2).
3. Are required to conduct a performance test.	Submit a notification of intent to conduct a performance test.	60 calendar days before the performance test is scheduled to begin.	§ 63.7(b)(1).
4. Are required to conduct a compliance demonstration that includes a performance test according to the requirements in Table 4 to this subpart.	Submit a Notification of Compliance Status, including the performance test results.	60 calendar days following the completion of the performance test, by the close of business.	§ 63.9(h) and § 63.10(d)(2).
5. Are required to conduct a compliance demonstration required in Table 6 to this subpart that does not include a performance test ( <i>i.e.</i> , compliance demonstrations for the work practice standards).	Submit a Notification of Compliance Status.	30 calendar days following the completion of the compliance demonstrations, by the close of business.	§ 63.9(h).
6. Request to use the routine control device maintenance alternative standard according to § 63.8570(d).	Submit your request .....	120 calendar days before the compliance date specified in § 63.8545.	
7. Own or operate an affected kiln that is subject to the work practice standard specified in Item 1 of Table 3 to this subpart, and you intend to use a fuel other than natural gas or equivalent to fire the affected kiln.	Submit a notification of alternative fuel use.	48 hours following the declaration of a period of natural gas curtailment or supply interruption, as defined in § 63.8665.	

As stated in § 63.8635, you must submit each report that applies to you according to the following table:

TABLE 10 TO SUBPART KKKKK OF PART 63—REQUIREMENTS FOR REPORTS

You must submit . . .	The report must contain . . .	You must submit the report . . .
1. A compliance report .....	<p>a. If there are no deviations from any emission limitations or work practice standards that apply to you, a statement that there were no deviations from the emission limitations or work practice standards during the reporting period. If there were no periods during which the CMS was out-of-control as specified in your OM&amp;M plan, a statement that there were no periods during which the CMS was out-of-control during the reporting period.</p> <p>b. If you have a deviation from any emission limitation (emission limit, operating limit) during the reporting period, the report must contain the information in § 63.8635(c)(8). If there were periods during which the CMS was out-of-control, as specified in your OM&amp;M plan, the report must contain the information in § 63.8635(d).</p>	<p>Semiannually according to the requirements in § 63.8635(b).</p> <p>Semiannually according to the requirements in § 63.8635(b).</p>
2. A report of alternative fuel use .....	The information in § 63.8635(g) .....	If you are subject to the work practice standards specified in Table 3 to this subpart, and you use an alternative fuel to fire an affected kiln, by letter within 10 working days after terminating the use of the alternative fuel.

As stated in § 63.8655, you must comply with the General Provisions in

§§ 63.1 through 63.16 that apply to you according to the following table:



TABLE 11 TO SUBPART KKKKK OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART KKKKK

Citation	Subject	Brief description	Applies to subpart KKKKK?
§ 63.1	Applicability	Initial applicability determination; applicability after standard established; permit requirements; extensions, notifications.	Yes.
§ 63.2	Definitions	Definitions for part 63 standards	Yes.
§ 63.3	Units and Abbreviations	Units and abbreviations for part 63 standards	Yes.
§ 63.4	Prohibited Activities	Compliance date; circumvention; severability	Yes.
§ 63.5	Construction/Reconstruction.	Applicability; applications; approvals	Yes.
§ 63.6(a)	Applicability	General Provisions (GP) apply unless compliance extension; GP apply to area sources that become major.	Yes.
§ 63.6(b)(1)–(4)	Compliance Dates for New and Reconstructed sources.	Standards apply at effective date; 3 years after effective date; upon startup; 10 years after construction or reconstruction commences for section 112(f).	Yes.
§ 63.6(b)(5)	Notification	Must notify if commenced construction or reconstruction after proposal.	Yes.
§ 63.6(b)(6)	[Reserved].		
§ 63.6(b)(7)	Compliance Dates for New and Reconstructed Area Sources That Become Major.	Area sources that become major must comply with major source standards immediately upon becoming major, regardless of whether required to comply when they were area sources.	Yes.
§ 63.6(c)(1)–(2)	Compliance Dates for Existing Sources.	Comply according to date in subpart, which must be no later than 3 years after effective date; for section 112(f) standards, comply within 90 days of effective date unless compliance extension.	Yes.
§ 63.6(c)(3)–(4)	[Reserved]		No.
§ 63.6(c)(5)	Compliance Dates for Existing Area Sources That Become Major.	Area sources that become major must comply with major source standards by date indicated in subpart or by equivalent time period (for example, 3 years).	Yes.
§ 63.6(d)	[Reserved]		No.
§ 63.6(e)(1)(i)	Operation & Maintenance	General Duty to minimize emissions	No. See § 63.8570(b) for general duty requirement.
§ 63.6(e)(1)(ii)	Operation & Maintenance	Requirement to correct malfunctions ASAP	No.
§ 63.6(e)(1)(iii)	Operation & Maintenance	Operation and maintenance requirements enforceable independent of emissions limitations.	Yes.
§ 63.6(e)(2)	[Reserved]		No.
§ 63.6(e)(3)	Startup, Shutdown, and Malfunction Plan (SSMP).	Requirement for startup, shutdown, and malfunction (SSM) and SSMP; content of SSMP.	No.
§ 63.6(f)(1)	Compliance Except During SSM.	You must comply with emission standards at all times except during SSM.	No.
§ 63.6(f)(2)–(3)	Methods for Determining Compliance.	Compliance based on performance test, operation and maintenance plans, records, inspection.	Yes.
§ 63.6(g)	Alternative Standard	Procedures for getting an alternative standard	Yes.
§ 63.6(h)	Opacity/VE Standards	Requirements for opacity and VE standards	No, not applicable.
§ 63.6(i)	Compliance Extension	Procedures and criteria for Administrator to grant compliance extension.	Yes.
§ 63.6(j)	Presidential Compliance Exemption.	President may exempt source category	Yes.
§ 63.7(a)(1)–(2)	Performance Test Dates	Dates for conducting initial performance testing and other compliance demonstrations for emission limits and work practice standards; must conduct 180 days after first subject to rule.	Yes.
§ 63.7(a)(3)	Section 114 Authority	Administrator may require a performance test under CAA section 114 at any time.	Yes.
§ 63.7(a)(4)	Notification of Delay in Performance Testing Due To Force Majeure.	Must notify Administrator of delay in performance testing due to force majeure.	Yes.
§ 63.7(b)(1)	Notification of Performance Test.	Must notify Administrator 60 days before the test	Yes.
§ 63.7(b)(2)	Notification of Rescheduling.	Must notify Administrator 5 days before scheduled date of rescheduled date.	Yes.
§ 63.7(c)	Quality Assurance (QA)/ Test Plan.	Requirements; test plan approval procedures; performance audit requirements; internal and external QA procedures for testing.	Yes.
§ 63.7(d)	Testing Facilities	Requirements for testing facilities	Yes.
§ 63.7(e)(1)	Conditions for Conducting Performance Tests.	Performance tests must be conducted under representative conditions. Cannot conduct performance tests during SSM; not a violation to exceed standard during SSM.	No, § 63.8595 specifies requirements. Yes.

TABLE 11 TO SUBPART KKKKK OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART KKKKK—Continued

Citation	Subject	Brief description	Applies to subpart KKKKK?
§ 63.7(e)(2)–(3)	Conditions for Conducting Performance Tests.	Must conduct according to subpart and EPA test methods unless Administrator approves alternative; must have at least three test runs of at least 1 hour each; compliance is based on arithmetic mean of three runs; conditions when data from an additional test run can be used.	Yes.
§ 63.7(e)(4)	Testing under Section 114	Administrator's authority to require testing under section 114 of the Act.	Yes.
§ 63.7(f)	Alternative Test Method	Procedures by which Administrator can grant approval to use an alternative test method.	Yes.
§ 63.7(g)	Performance Test Data Analysis.	Must include raw data in performance test report; must submit performance test data 60 days after end of test with the notification of compliance status.	Yes.
§ 63.7(h)	Waiver of Tests	Procedures for Administrator to waive performance test.	Yes.
§ 63.8(a)(1)	Applicability of Monitoring Requirements.	Subject to all monitoring requirements in subpart	Yes.
§ 63.8(a)(2)	Performance Specifications	Performance Specifications in appendix B of 40 CFR part 60 apply.	Yes.
§ 63.8(a)(3)	[Reserved]		No.
§ 63.8(a)(4)	Monitoring with Flares	Requirements for flares in § 63.11 apply	No, not applicable.
§ 63.8(b)(1)	Monitoring	Must conduct monitoring according to standard unless Administrator approves alternative.	Yes.
§ 63.8(b)(2)–(3)	Multiple Effluents and Multiple Monitoring Systems.	Specific requirements for installing and reporting on monitoring systems.	Yes.
§ 63.8(c)(1)	Monitoring System Operation and Maintenance.	Maintenance consistent with good air pollution control practices.	Yes.
§ 63.8(c)(1)(i)	Routine and Predictable SSM.	Reporting requirements for SSM when action is described in SSMP.	No.
§ 63.8(c)(1)(ii)	SSM not in SSMP	Reporting requirements for SSM when action is not described in SSMP.	Yes.
§ 63.8(c)(1)(iii)	Compliance with Operation and Maintenance Requirements.	How Administrator determines if source complying with operation and maintenance requirements.	No.
§ 63.8(c)(2)–(3)	Monitoring System Installation.	Must install to get representative emission and parameter measurements.	Yes.
§ 63.8(c)(4)	CMS Requirements	Requirements for CMS	No, § 63.8600 specifies requirements.
§ 63.8(c)(5)	Continuous Opacity Monitoring System (COMS) Minimum Procedures.	COMS minimum procedures	No, not applicable.
§ 63.8(c)(6)	CMS Requirements	Zero and high level calibration check requirements	Yes.
§ 63.8(c)(7)–(8)	CMS Requirements	Out-of-control periods	Yes.
§ 63.8(d)(1) and (2)	CMS Quality Control	Requirements for CMS quality control	Yes.
§ 63.8(d)(3)	CMS Quality Control	Written procedures for CMS	No, § 63.8575(b)(9) specifies requirements.
§ 63.8(e)	CMS Performance Evaluation.	Requirements for CMS performance evaluation	Yes.
§ 63.8(f)(1)–(5)	Alternative Monitoring Method.	Procedures for Administrator to approve alternative monitoring.	Yes.
§ 63.8(f)(6)	Alternative to Relative Accuracy Test.	Procedures for Administrator to approve alternative relative accuracy test for continuous emission monitoring systems (CEMS).	No, not applicable.
§ 63.8(g)	Data Reduction	COMS and CEMS data reduction requirements	No, not applicable.
§ 63.9(a)	Notification Requirements	Applicability; State delegation	Yes.
§ 63.9(b)	Initial Notifications	Requirements for initial notifications	Yes.
§ 63.9(c)	Request for Compliance Extension.	Can request if cannot comply by date or if installed BACT/LAER.	Yes.
§ 63.9(d)	Notification of Special Compliance Requirements for New Source.	For sources that commence construction between proposal and promulgation and want to comply 3 years after effective date.	Yes.
§ 63.9(e)	Notification of Performance Test.	Notify Administrator 60 days prior	Yes.
§ 63.9(f)	Notification of VE/Opaicity Test.	Notify Administrator 30 days prior	No, not applicable.
§ 63.9(g)(1)	Additional Notifications When Using CMS.	Notification of performance evaluation	Yes.
§ 63.9(g)(2)–(3)	Additional Notifications When Using CMS.	Notification of COMS data use; notification that relative accuracy alternative criterion were exceeded.	No, not applicable.
§ 63.9(h)	Notification of Compliance Status.	Contents; submittal requirements	Yes.

TABLE 11 TO SUBPART KKKKK OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART KKKKK—Continued

Citation	Subject	Brief description	Applies to subpart KKKKK?
§ 63.9(i)	Adjustment of Submittal Deadlines.	Procedures for Administrator to approve change in when notifications must be submitted.	Yes.
§ 63.9(j)	Change in Previous Information.	Must submit within 15 days after the change	Yes.
§ 63.10(a)	Recordkeeping/Reporting	Applicability; general information	Yes.
§ 63.10(b)(1)	General Recordkeeping Requirements.	General requirements	Yes.
§ 63.10(b)(2)(i)	Records Related to SSM	Recordkeeping of occurrence and duration of startups and shutdowns.	No.
§ 63.10(b)(2)(ii)	Records Related to SSM	Recordkeeping of failures to meet a standard	No. See § 63.8640(c)(2) for recordkeeping of (1) date, time and duration; (2) listing of affected source or equipment, and an estimate of the volume of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure.
§ 63.10(b)(2)(iii)	Records Related to SSM	Maintenance records	Yes.
§ 63.10(b)(2)(iv)–(v)	Records Related to SSM	Actions taken to minimize emissions during SSM	No.
§ 63.10(b)(2)(vi)–(xii) and (xiv).	CMS Records	Records when CMS is malfunctioning, inoperative or out-of-control.	Yes.
§ 63.10(b)(2)(xiii)	Records	Records when using alternative to relative accuracy test.	No, not applicable.
§ 63.10(b)(3)	Records	Applicability Determinations	Yes.
§ 63.10(c)(1)–(15)	Records	Additional records for CMS	No, §§ 63.8575 and 63.8640 specify requirements.
§ 63.10(d)(1) and (2)	General Reporting Requirements.	Requirements for reporting; performance test results reporting.	Yes.
§ 63.10(d)(3)	Reporting Opacity or VE Observations.	Requirements for reporting opacity and VE	No, not applicable.
§ 63.10(d)(4)	Progress Reports	Must submit progress reports on schedule if under compliance extension.	Yes.
§ 63.10(d)(5)	SSM Reports	Contents and submission	No. See § 63.8635(c)(8) for malfunction reporting requirements.
§ 63.10(e)(1)–(3)	Additional CMS Reports	Requirements for CMS reporting	No, §§ 63.8575 and 63.8635 specify requirements.
§ 63.10(e)(4)	Reporting COMS data	Requirements for reporting COMS data with performance test data.	No, not applicable.
§ 63.10(f)	Waiver for Recordkeeping/Reporting.	Procedures for Administrator to waive	Yes.
§ 63.11	Flares	Requirement for flares	No, not applicable.
§ 63.12	Delegation	State authority to enforce standards	Yes.
§ 63.13	Addresses	Addresses for reports, notifications, requests	Yes.
§ 63.14	Incorporation by Reference	Materials incorporated by reference	Yes.
§ 63.15	Availability of Information	Information availability; confidential information	Yes.
§ 63.16	Performance Track Provisions.	Requirements for Performance Track member facilities	Yes.

[FR Doc. 2015–25724 Filed 10–23–15; 8:45 am]



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Part IV

Department of Interior

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National Park Service

36 CFR Parts 1 and 9

General Provisions and Non-Federal Oil and Gas Rights; Proposed Rule

**DEPARTMENT OF THE INTERIOR****National Park Service****36 CFR Parts 1 and 9**

[NPS–WASO–NRSS–15890; PX.XVPAD0520.00.1]

RIN 1024–AD78

**General Provisions and Non-Federal Oil and Gas Rights**

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

**SUMMARY:** We are proposing to update our service-wide regulations governing the exercise of non-federal oil and gas rights, to improve our ability to protect park resources, values, and visitors from potential impacts associated with non-federal oil and gas operations located within National Park Service units. The proposed rule would also make the regulations consistent with existing policies and practices, and update the format to improve clarity and simplify application and compliance for oil and gas operators and our employees.

**DATES:** Comments on the proposed rule must be received by December 28, 2015. Comments on the information collection requirements must be received by November 25, 2015

**ADDRESSES:** If you wish to comment on this proposed rule, you may submit your comments, identified by Regulation Identifier Number (RIN) 1024–AD78, by either of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Edward O. Kassman, Jr., Geologic Resources Division, National Park Service, P.O. Box 25287, Denver, Colorado 80225.

*Instructions:* Your comment must include the agency name and RIN (1024–AD78) for this rulemaking. Comments will be posted to <http://www.regulations.gov>, including any personal information provided. For additional instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document.

- Send your comments and suggestions on the information collection requirements to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov) (email). You may review all documents submitted to OMB to support the proposed new information

collection requirements online at <http://www.reginfo.gov>. Follow the instructions to review Department of the Interior collections under review by OMB. Please provide a copy of your comments to the Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Drive, Room 2C114, Mail Stop 242, Reston, VA 20192 (mail); or [madonna\\_baucum@nps.gov](mailto:madonna_baucum@nps.gov) (email). Please reference “1024–O&G” in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:**

Edward O. Kassman, Jr., Geologic Resources Division, National Park Service, P.O. Box 25287, Denver, Colorado 80225; [edward\\_kassman@nps.gov](mailto:edward_kassman@nps.gov); 303–969–2146.

**SUPPLEMENTARY INFORMATION:****Executive Summary**

The National Park Service (NPS) is proposing to update the existing regulations at 36 CFR part 9, subpart B (9B regulations), which govern the exercise of non-federal oil and gas rights in NPS units, to improve the effectiveness of the regulations in protecting park resources and values and to improve the clarity of the regulations for both operators and the NPS.

Key updates to the regulations would include:

- Elimination of two regulatory provisions that exempt approximately 60% of the oil and gas operations located within the national park system;
- Elimination of the cap on financial assurance (bonding);
- Application of the penalty provisions of 36 CFR 1.3;
- Incorporation of fees for new access beyond that held as part of the operator’s mineral right;
- Addition of a new well-plugging provision;
- Clarification that access to oil and gas properties in Alaska is controlled by 43 CFR part 36, which implements provisions of the Alaska National Interest Lands Conservation Act;
- Clarification of well stimulation information requirements and operating standards;
- Incorporation of a new format that makes it easier to identify the information requirements for particular types of operations;
- Incorporation of a new format for operating standards so that both the NPS and the operator can readily identify what standards apply to particular operations;
- Elimination of redundant definitions and provisions;
- Consolidation of existing regulatory provisions; and

- Codification of some existing agency policies and practices.

A detailed discussion of all changes to the regulations is contained in the section-by-section analysis.

**Background**

On December 8, 1978, the NPS promulgated the current regulations in 36 CFR part 9, subpart B (43 FR 57825), which govern the exercise of non-federal oil and gas rights in units of the National Park System (NPS units).

*Current 9B Regulations*

The current 9B regulations apply to all activities associated with non-federal oil and gas exploration and development inside NPS unit boundaries where access is on, across, or through federally owned or controlled lands or waters (36 CFR 9.30(a)). Under the existing regulations, an operator must obtain our approval of a proposed plan of operations before commencing non-federal oil and gas operations in an NPS unit (36 CFR 9.32(b)). This requirement covers exploration, drilling, production, transportation, plugging, and reclamation operations.

The plan of operations is a prospective operator’s blueprint of all intended activities and is our primary means for evaluating the operation’s potential adverse impacts on park resources and values. It must show that the operator is exercising a bona fide property right to non-federal oil and gas in an NPS unit (36 CFR 9.36(a)(2)). The plan of operations must also describe:

- The proposed operation, including the equipment, methods, and materials to be used in the operation;
- Access to the site;
- Mitigation measures that will be implemented to protect NPS resources and values;
- Environmental conditions in the vicinity of the site;
- Alternatives to the proposal; and
- The environmental impacts of the proposed operation (36 CFR 9.36(a)).

In addition to the plan of operations, the operator must submit a performance bond to ensure that funds are available to reclaim a site if the operator defaults on its obligations under an approved plan (36 CFR 9.48). In order to make the regulatory process as efficient and transparent as possible, we work collaboratively with operators early in their planning process to provide guidance on information requirements, alternative area of operations locations, and potential mitigation and avoidance measures.

As part of our approval process, we coordinate and consult with a variety of

state and other federal regulatory agencies to ensure that approval complies with applicable federal statutes, such as the National Environmental Policy Act of 1969, the Endangered Species Act, and the National Historic Preservation Act.

Operators conducting non-federal oil and gas operations in NPS units must also comply with all applicable state and local laws (36 CFR 9.36(a)(15)). Although state oil and gas regulations may contain provisions designed to protect natural resources (e.g., surface and groundwater), their primary focus is on oil and gas production and protection of associated ownership interests. The purpose and focus of the 9B regulations is to protect the National Park System's natural and cultural resources and visitor values and safety.

When the NPS Regional Director has determined that the proposal meets the requirements contained in the regulations and the NPS has completed the required environmental compliance, the Regional Director will approve the plan (36 CFR 9.37). The approved plan is the operator's authorization to conduct its operation in an NPS unit (36 CFR 9.32(a)).

During the life of an oil or gas operation in a park, the park manager has the authority to monitor and ensure compliance with the approved plan of operations (36 CFR 9.37(f)). If there is a change in circumstances, the NPS or the operator can make a request to supplement and modify the plan (36 CFR 9.40). The 9B regulations authorize us to enforce the terms of the plan, as may be necessary, by suspending operations or revoking plan approval (36 CFR 9.51). The operator may appeal a Regional Director's decision (36 CFR 9.49).

#### *Authority To Promulgate the Regulations*

The authority to promulgate these regulations is the statute commonly known as the NPS Organic Act (54 U.S.C. 100101 *et seq.*) as well as other statutes governing the administration of the National Park System. In the NPS Organic Act, Congress directs us to "promote and regulate the use of the National Park System by means and measures that conform to the fundamental purpose of the System units, which purpose is to conserve the scenery, natural and historic objects, and wild life in the System units and to provide for the enjoyment of the scenery, natural and historic objects, and wild life in such manner and by such means as will leave them unimpaired for the enjoyment of future generations." The Organic Act also gives

us the authority to promulgate regulations "necessary or proper for the use and management of System units." (54 U.S.C. 100751). This includes the authority to regulate the exercise of non-federal oil and gas rights within park boundaries for the purpose of protecting the resources and values administered by the NPS.

In addition, the enabling legislation for several NPS units contains specific provisions authorizing us to regulate the exercise of non-federal oil and gas rights. In the authority section of the proposed rule, we list the individual enabling statutes that address non-federal oil and gas rights in specific NPS units.

Our authority to promulgate the 9B regulations has been recognized as a valid exercise of NPS's Organic Act authority by a U.S. District Court and the Fifth Circuit Court of Appeals. *See Dunn-McCampbell Royalty Interest v. National Park Service*, 964 F. Supp. 1125 (S.D. Tex. 1995), and *Dunn-McCampbell Royalty Interest v. National Park Service*, 630 F.3d 431 (5th Cir. 2011). Courts have consistently recognized NPS's authority to regulate non-federal interests within units of the National Park System. *See, e.g., United States v. Vogler*, 859 F.2d 638 (9th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989); *United States v. Garfield County*, 122 F. Supp. 2d 1201 (D. Utah 2000). *See also Southern Utah Wilderness Alliance v. Bureau of Land Management*, 425 F.3d 735, 746–47 (10th Cir. 2005).

As explained below, the NPS proposed rule uses most of the language from BLM's hydraulic fracturing information requirements at 43 CFR 3162.3–3(d)(1) through (7), which BLM recently promulgated under authority of the Mineral Leasing Act, 30 U.S.C. 189, the Federal Land Policy and Management Act, 43 U.S.C. 1701 *et seq.*, and other BLM authorities. On September 30, 2015, the U.S. District Court for the District of Wyoming preliminarily enjoined these regulations. *State of Wyoming, et al. v. U.S. Department of the Interior*, Case No. 2:15–CV–043–SWS. This litigation is ongoing and the status of the litigation will be addressed by NPS in development of its final rule. NPS will consider any comments addressing NPS' authority to promulgate the proposed rules concerning well stimulation operations within units of the National Park System, as well as comments on the proposed requirements (see in particular, proposed §§ 9.88–9.90 and 9.118).

For NPS units in Alaska that were established under the Alaska National

Interest Lands Conservation Act (ANILCA), access to non-federal property is governed by the regulations at 43 CFR part 36, which implement section 1110(b) of ANILCA. This regulation gives operators the option to file for such access as part of their plans of operations, but they also may use a SF 299 as provided in the 43 CFR part 36 regulations. This is similar to the process applicable to mining claims under those regulations and the NPS regulations at 36 CFR part 9, subpart A. We also note that because these regulations are generally applicable to NPS units nationwide and to non-federal interests in those units, they are not "applicable solely to public lands within [units established under ANILCA]," and thus are not affected by section 103(c) of ANILCA. *See Sturgeon v. Masica*, 768 F.3d 1066, 1077–78 (9th Cir. 2014).

A unique provision exists under the Big Cypress National Preserve Addition Act of 1988, at 16 U.S.C. 698m–4. This provision states that the Secretary shall promulgate rules and regulations governing the exploration for and development and production of non-Federal interests in oil and gas located within the boundaries of the Big Cypress National Preserve and the Addition, and that such rules and regulations may be made by appropriate amendment to or in substitution of the rules and regulations respecting non-Federal oil and gas rights (currently codified at 36 CFR 9.30 *et seq.* (1986)). 16 U.S.C. 698m–4(a).

The Addition Act also authorizes the Secretary prior to the promulgation of rules or regulations under this section, to enter into interim agreements with owners of non-Federal oil and gas interests governing the conduct of oil and gas exploration, development or production activities within the boundary of the Addition. 16 U.S.C. 698m–4(e).

Consistent with that authority, the present oil and gas operations within the Addition Area are controlled under the terms of the *Agreement Governing The Exercise Of Reserved Oil And Gas Rights Of Collier Enterprises And Barron Collier Company*, which is Appendix 6 to the *Agreement Among the United States of America, Collier Enterprises, Collier Development Corporation, and Barron Collier Company* (May 12, 1988). If promulgated as proposed, the rule would supersede Appendix 6.

#### *Non-Federal Oil and Gas Rights in NPS Units*

Non-federal oil and gas rights exist within NPS units in situations where

the United States does not own the oil and gas interest, either because:

- The United States acquired the property from a grantor that did not own the oil and gas interest; or
- The United States acquired the property from a grantor that reserved the oil and gas interest from the conveyance.

Non-federal oil and gas interests can be held by individuals; nonprofit organizations; corporations, including Alaska Native corporations; or state and local governments. Interests in non-federal oil and gas are property rights that may only be taken for public use with payment of just compensation in accordance with the Fifth Amendment of the U.S. Constitution. Accordingly, from their initial promulgation, the existing regulations at 36 CFR 9.30(a) have stated that they are “not intended to result in the taking of a property interest, but rather to impose reasonable regulations on activities that involve and affect federally owned lands.” The proposed rule includes this same provision.

There are currently 534 non-federal oil and gas operations in a total of 12 NPS units. These units are: Alibates Flint Quarries National Monument (Texas), Aztec Ruins National Monument (New Mexico), Big Cypress National Preserve (Florida), Big Thicket National Preserve (Texas), Big South Fork National River and Recreation Area (Tennessee/Kentucky), Cumberland Gap National Historical Park (Tennessee), Cuyahoga Valley National Park (Ohio), Gauley River National Recreation Area (West Virginia), Lake Meredith National Recreation Area (Texas), New River Gorge National River (West Virginia), Obed Wild and Scenic River (Tennessee), and Padre Island National Seashore (Texas).

Based on the presence of split estates, exploration and production occurring on adjacent or nearby lands, and likely future increases in energy prices, we believe that non-federal oil and gas operations within park boundaries could affect up to 30 additional NPS units.

#### *Summary of Potential Impacts From Oil and Gas Operations on NPS Resources and Values*

The types of non-federal oil and gas operations conducted in NPS units generally include: Geophysical (seismic) exploration; exploratory well drilling; field development well drilling; oil and gas well production operations, including installation and operation of well flowlines and gathering lines; well plugging and abandonment; and site reclamation.

Oil and gas activities may adversely impact NPS unit resources in some or all of the following manners:

- Surface water quality degradation from spills, storm water runoff, erosion, and sedimentation. Through site inspections the NPS has documented 26 instances of sites with surface contamination;
  - Soil and ground water contamination from existing drilling mud pits, poorly constructed wells, spills, and leaks. Through site inspections the NPS has documented 47 instances of sites with wellhead leaks, pump jack leaks, tank battery leaks, and operations and maintenance spills;
  - Air quality degradation from dust, natural gas flaring, hydrogen sulfide gas, and emissions from production operations and vehicles. Through site inspections the NPS has documented 14 instances of notable odors emanating from the wellhead;
    - Increased noise from seismic operations, blasting, construction, oil and gas drilling and production operations. Through site inspections the NPS has documented 6 instances of noise issues from well pad equipment;
    - Noise and human presence effects on wildlife behavior, breeding, and habitat utilization;
    - Disruption of wildlife migration routes;
    - Adverse effects on sensitive and endangered species. Through site inspections the NPS has documented 15 sites with sensitive species or habitat;
    - Viewshed intrusion by roads, traffic, drilling equipment, production equipment, pipelines, etc.;
    - Night sky intrusion from artificial lighting and gas flares;
    - Disturbance to archeological and cultural resources from blasting associated with seismic exploration and road/site preparation, maintenance activities, or by spills. Through site inspections the NPS has documented 6 sites with associated cultural resources; and
    - Visitor safety hazards from equipment, pressurized vessels and lines, presence of hydrogen sulfide gas, and leaking oil and gas that can create explosion and fire hazards. Through site inspections the NPS has documented 62 instances of visitor safety hazards.

Examples of documented impacts can be found in many parks. For example, at Big South Fork natural gas fired pump jack engines have caused notable noise at visitor overlooks that are 2 to 3 miles away. Simple mitigation such as a corrugated steel fence would abate this impact, however, due to the well's grandfathered status; the NPS is unable

to require this mitigation and forced to accept this unnecessary impact.

Another example of unnecessary impacts can be found at Aztec Ruins National Monument where an operation exempt from the 9B regulations due to the grandfathered exemption contained a road that traversed an undeveloped and buried archeological site. When this well lost its grandfathered status, the NPS was able to require the new operator to conduct a cultural resource survey to determine the impacts to the site. As mitigation the operator installed a layer of dirt between the resource and the road base to protect the resources. Unfortunately, in this case the damage was already done and it did not make sense to move the road but the resource is better preserved for future enjoyment.

#### **Summary of Advance Notice of Proposed Rulemaking Comments**

On November 25, 2009, we issued an Advance Notice of Proposed Rulemaking (ANPRM) (74 FR 61597) to assist us in developing the proposed rule. The ANPRM and the analysis of public comments for the ANPRM are available online at [http://www.nature.nps.gov/geology/oil\\_and\\_gas/9b\\_index.cfm#prev\\_docs](http://www.nature.nps.gov/geology/oil_and_gas/9b_index.cfm#prev_docs). Although we are proposing updates to all of subpart B, the ANPRM focused its request for public comment on six topics that we identified as major areas of concern:

- (1) Regulation of previously exempt operations;
- (2) Directional drilling;
- (3) Operating standards;
- (4) Financial assurance;
- (5) Access fees; and
- (6) Assessments for non-compliance.

We received comments from oil and gas owners and operators (2), Alaska Native Corporations (2), unaffiliated private citizens (6), and environmental organizations (10), including 1,477 comments from members of the Sierra Club in the form of personal comments added to a form letter.

The majority of commenters were in favor of strengthening and expanding the regulations to better protect park resources and values. Some commenters requested that we not expand the scope of the 9B regulations, while others questioned the legality of regulating non-federal oil and gas operations in parks. Additionally, some comments asked us to consider the impacts of potential natural gas development of the Marcellus Shale formation in the eastern United States.

More information on the ANPRM and these comments is available at [http://www.nature.nps.gov/geology/oil\\_and\\_](http://www.nature.nps.gov/geology/oil_and_)

[gas/documents/2011-01-11%20ANPR\\_Comment\\_Analysis\\_Report.pdf](http://gas/documents/2011-01-11%20ANPR_Comment_Analysis_Report.pdf).

### Draft Environmental Impact Statement

We have prepared a draft environmental impact statement (DEIS), which will be published shortly after this proposed rule. The DEIS will be available for review and public comment at <http://parkplanning.nps.gov/DEIS9B> by clicking on the link entitled “Document List.”

The DEIS describes three alternatives: Alternative A—No action; Alternative B—preferred alternative and proposed rule; and Alternative C. Alternative C would include all the proposed changes in alternative B, except that it would expand NPS jurisdiction under the regulations to encompass surface and subsurface directional drilling operations outside the boundary of the park; would provide an operator, under limited circumstances, with an exemption to the operations permit requirement for operations located wholly on non-federally owned land within a park boundary; and would hold mineral owners and operators jointly and severally liable for compliance with an operations permit or other applicable provisions of the 9B regulations.

### Section-by-Section Analysis

Proposed rule	Existing regulation
§§ 9.30 through 9.33 <i>Purpose and Scope.</i>	§ 9.30(a), (b), (c). § 9.32(a), (b). § 9.36(a)(2).

#### §§ 9.30 through 9.33—Purpose and Scope

##### *Access on, Across, or Through Federally Owned or Controlled Lands or Waters*

The existing 9B regulations apply only when an operator’s “access [is] on, across, or through federally owned or controlled lands or waters.” Seventy-eight operations (15% of all oil and gas operations in NPS units) do not require access on, across, or through federally owned or controlled lands or waters and are thus outside the scope of the 9B regulations. These operators are not required to obtain an approved NPS plan of operations, post financial assurance, or otherwise comply with this subpart to protect park resources and values. However, our experience over the past three decades has demonstrated that these operations have the potential to have adverse effects on NPS resources, values, and visitor health and safety. Through site inspections, the NPS has found at least 10 instances of sites with oil spills or

leaks resulting in contamination of soils and water.

For example, a poorly operated oil tank battery within the boundary of Big Thicket National Preserve that is currently exempt because it does not require access across federally owned land has contaminated storm water runoff that runs into adjacent federally owned land near Village Creek. Another example is a large compressor that was located on nonfederal lands within the boundary of Big South Fork National River and Recreation Area. The compressor causes unabated noise for which the NPS is unable to require mitigation due to the current scope of the regulations.

In 1978 the NPS made a policy choice to limit the application of its non-federal-oil-and-gas regulatory program to operators requiring access on, across, or through federally owned or controlled lands or waters. That choice was not required by any statutory provision. The NPS now believes that it is appropriate to revisit and modify the application of its regulations.

Under the proposed rule at §§ 9.30 through 9.33, all operators conducting operations within NPS boundaries would be subject to permit requirements. The permitting process would include an evaluation to determine whether, and the extent to which, such operations would have an adverse effect on federally owned or administered lands, waters, or resources of NPS units, visitor uses or experiences, or visitor or employee health and safety. These operations would also be subject to measures to mitigate such adverse effects, as well as to the financial assurance and reclamation requirements.

##### *Regulations Not Intended To Result in a Taking*

Proposed § 9.30(c) retains the existing regulatory language from § 9.30(a) that the intention of this subpart is to reasonably regulate such activities, but not to result in a taking of private property. Although the NPS has placed park-protecting mitigation measures on proposed operations, we have never, in the more than 35 years of applying this subpart, denied prospective operators access to exercise their non-federal oil and gas rights. We will continue to work with operators to ensure they have reasonable access to their operations and that park resources and values are protected without resulting in a taking in violation of the Fifth Amendment of the United States Constitution.

##### *Interests Regulations Are Designed To Protect*

The existing regulations inconsistently describe the interests that the regulations are designed to protect. The proposed rule would clarify and consistently state that the 9B regulations are designed to protect federally owned or administered lands, waters, or resources of NPS units, visitor uses or experiences, and visitor or employee health and safety. The proposed rule would replace the phrase “federally owned or controlled” with the phrase “federally owned or administered” to be consistent with the terminology we use in our general regulations, at 36 CFR 1.2, and 36 CFR 1.4(a) (definition of “National Park System”), and in our NPS Management Policies (2006).

##### *Operations Subject to These Regulations*

Proposed § 9.31(a) applies these regulations to all nonfederal oil and gas operations within the boundary of an NPS unit. Proposed § 9.31(b) covers those operations that become part of an NPS unit either by boundary expansion or establishment of a new NPS unit. Proposed § 9.31(c) covers those operations that have accessed oil and gas rights from a surface location outside the park boundary but due to a boundary expansion or establishment of a new unit, the surface location is now within an NPS unit. Those operations covered under § 9.31(b) and (c) would be required to follow the same requirements and procedures as previously exempt operations at §§ 9.50 through 9.53.

##### *Type of Authorization Required*

Proposed § 9.32(a) would clarify that an operator must have either a temporary access permit or an operations permit before conducting either reconnaissance surveys or operations in an NPS unit.

##### *Demonstration of Valid Existing Right*

The existing regulation contains a requirement that operators demonstrate that they hold valid rights to conduct activities. The proposed rule would move this requirement to § 9.32(b) under “Scope and Purpose” to clarify that all operators must demonstrate “up front” that they hold a valid existing right to conduct operations in an NPS unit. Unless an operator can demonstrate a valid existing right to conduct operations, we would not undertake formal review of an operator’s operations permit application.



*Elimination of Unnecessary Regulatory Language*

The proposed rule would delete existing § 9.30(b) and (c). We view these sections as advisory and more appropriate for inclusion in guidance materials that we will develop following the promulgation of this subpart.

*Operations Authorized Under Previous 9B Regulations*

Proposed § 9.33(a) would authorize an operator that currently holds an approved plan of operations under the existing regulations to continue operations, subject to the applicable provisions of the regulations.

Proposed § 9.33(b) would authorize an operator that remains exempt from the plan of operations requirement because it is currently accessing oil and gas rights inside a park boundary from a surface location outside the park boundary to continue operations, subject to the General Terms and Conditions and the Compliance Procedure provisions of the regulations.

Proposed rule	Existing regulation
§ 9.40 Definitions .....	§§ 9.31(a) through (o), § 9.32(c) and (d).

**§ 9.40 Definitions**

The proposed rule would organize the definitions in alphabetical order to make this section more user-friendly. The proposed rule would also delete several redundant definitions because the same terms are defined at 36 CFR 1.4. The definitions proposed for deletion are: “Secretary” (existing § 9.31(a)), “Director” (existing § 9.31(b)), “Person” (existing § 9.31(e)), and “Superintendent” (existing § 9.31(f)). The proposed rule also deletes two definitions that are no longer applicable: “Commercial Vehicle” (existing § 9.31(g)) and “Statement for Management” (existing § 9.31(o)).

*New or Revised Definitions*

The proposed rule would add a new term, “Area of Operations,” to the Definition section to replace the term “Site,” at existing § 9.31(m). The new term would identify all areas where an operator is authorized to conduct its activities, including access to the operations site.

The proposed rule would expand the definition of “Contaminating Substances,” at existing § 9.31(n), to include other toxic or hazardous substances. The NPS is proposing to remove the term “waste” from this definition and include a new separate definition of waste in the proposed rule.

The proposed rule would revise the definition of the term “Unit” to “NPS unit” and make this term the same as “National Park System (Park Area)” found at 36 CFR 1.4(a).

The proposed rule would change the definition of “Operations” at existing § 9.31(c), to clarify that “access” includes “any means of ingress to or egress from an area of operations.” The NPS intends this change to cover any and all types of access, including access via aircraft, to and from an area of operations. For access via aircraft, the NPS regulates only the time, place, and manner of aircraft landing on NPS administered lands or waters within an NPS unit. The NPS does not regulate aircraft overflight under the 9B regulations. Accordingly, the NPS would remove existing § 9.32(c), which regulates 9B aircraft access. The proposed rule would also delete existing § 9.32(d). This access is controlled by NPS commercial vehicle regulations at 36 CFR 5.6(c).

The definition of “Operations” also clarifies that the operation of a flowline or a gathering line is included within this definition, but not the installation, operation, or maintenance of oil and gas pipelines that are located within the park under authority of a deeded easement or other right-of-way, which are not covered by the 9B regulations.

The proposed rule would add a new term “Operations Permit” as the permitting vehicle for all operations. An operations permit will be a special use permit subject to cost recovery under 54 U.S.C. 103104, which authorizes the NPS to recover all costs associated with providing necessary services associated with special use permits.

The proposed rule would update the definition of “Operator” at existing § 9.31(d) by clarifying that responsibilities and liability under this subpart can attach to the operator or the operator’s agents, assignees, designees, lessees, or representatives.

The proposed rule defines “owner” as a “person” which incorporates the definition of “person” from § 1.4.

The proposed rule adds a new definition of “Previously Exempt Operation” to clarify which types of operations are covered by proposed §§ 9.50 through 9.53. This definition does not include those operations where the operator was granted an exemption under existing § 9.32(e) to the plan of operations requirement by the NPS because it accessed oil and gas rights inside the park boundary from a surface location outside the park boundary (which are covered by proposed § 9.33(b)).

The proposed rule would add a new term “Reconnaissance Survey” to clarify that reconnaissance surveys do not include surface disturbance activities, except minimal disturbance necessary to perform surveys.

The proposed rule would add a new term “Right to Operate” that incorporates much of the language in existing § 9.36(a)(2) (right to operate description for a Plan of Operations). The new definition would clarify that an operator’s right-to-operate documentation must demonstrate the proposed activities are within the scope of that right.

The proposed rule would add a new term “Technologically feasible, least damaging methods” to describe the general standard that all operators must satisfy when meeting applicable operating standards.

The proposed rule would add a new term “Temporary Access Permit” to clarify that under the proposed rule the NPS would grant temporary access only for reconnaissance surveys and to collect basic information necessary to prepare a permit application.

The proposed rule would add a new term “Third-Party Monitor” to identify a third-party monitor’s necessary qualifications.

The proposed rule would add a new term “Usable water” to describe the criteria that the NPS uses to identify protected sources of groundwater.

The proposed rule would add a new term “Waste” to differentiate between “waste” and “contaminating substances.”

The proposed rule would add a new set of terms “We and us” to refer to the National Park Service.

The proposed rule would add a definition of “You” to be consistent with the plain language format of this subpart.

Proposed rule	Existing regulation
§§ 9.50 through 9.53 Previously Exempt Operations.	§ 9.30(a), § 9.33.

**§§ 9.50 Through 9.53—Previously Exempt Operations**

The proposed rule would create a new section “Previously Exempt Operations” to describe the process for bringing all previously exempt operations into compliance with the proposed rule. These include operations that do not require access on, across, or through federal lands (15% of total operations are currently exempt due to existing § 9.30, see above discussion) and grandfathered operations (45% of total

operations are currently exempt due to existing § 9.33).

#### *Grandfathered Operations*

Under existing § 9.33, operators who were conducting operations at the time the regulations became effective (January 8, 1979) and who had already obtained a valid federal or state permit were “grandfathered.” These operators were not required to obtain an approved plan of operations; comply with NPS operating standards, including reclamation of their area of operations to NPS standards; or post a reclamation bond. The Superintendent does have authority under existing § 9.33(c) to suspend grandfathered operations if there is an “immediate threat of significant injury to federally owned or controlled lands or waters.” The NPS has used this authority, in limited cases, to suspend grandfathered operations—suspensions that would not have been necessary if the operators were proactively meeting NPS standards. For example, at Big Thicket National Preserve, the NPS suspended two grandfathered operations that were causing unnecessary impacts, including poor spill prevention equipment and methods resulting in localized contamination to soils, lack of proper vegetation control that increased risk of fire, and poor site security that presented risks to visitor health and safety. Under existing § 9.33(a)(1), when the existing federal or state permit expires and the operator is issued a new permit, the operator then becomes subject to all provision of the 9B regulations.

In 1978 the NPS expected that over time the permits associated with these operators would expire and that the operators would then be required to come into compliance with the 9B regulations. However, the rate of permit expiration has been much slower than anticipated. This has left approximately 45% of operations (241 wells service-wide) still exempt from the regulations over thirty years later, causing unnecessary and readily avoidable impacts to NPS-administered resources and values. For example, through site inspections, the NPS has found 20 instances of hydrocarbon spills and leaks, 3 instances of gas venting, 2 instances of notable noise issues, and 3 instances of notable hydrocarbon odors emanating from the well site. The grandfather exemption is not required by statute, and was a discretionary policy choice by the NPS to provide for a “smooth and fair phase in of [the 1978] regulations.” (43 FR 57822)

This rulemaking is intended to ensure that all operations within NPS units are

conducted in a manner that protects park resources and values. A majority of comments to the ANPRM regarding previously exempt operations suggested that to achieve this goal, the NPS’s new rule should require previously exempt operators to obtain an operations permit. The NPS agrees, and has tailored the process for obtaining an operations permit to the specific circumstances presented by previously exempt operations.

#### *Procedure for Bringing Previously Exempt Operations Into Compliance*

Proposed § 9.50(a) would establish that previously exempt operators must obtain an Operations Permit.

In proposed § 9.51, the NPS describes the information that a previously exempt operator would be required to submit to the NPS to obtain an operations permit. For a new oil and gas operation in an NPS unit, the NPS requires an operator to submit the information necessary for the NPS to select the least damaging locations for its access route, drilling site, production facilities, and gathering-line routes. However, for previously exempt operations, the operator’s well has already been drilled and the area of operations (access route, well site, production facilities, and routes for gathering lines) has already been established. Therefore, under proposed § 9.51, within 90 days after the effective date of this subpart, operators must provide the NPS with information that would enable the NPS to evaluate the previously exempt operation to determine whether these operations are being conducted in compliance with NPS operating standards. This information is also needed for future monitoring of the approved operations to ensure compliance with NPS operating standards. The information requirements under this proposed section also require operators to submit information if they intend to change existing operations (*e.g.*, if they intend to plug their wells).

Once the operator provides the information required under proposed § 9.51, the NPS would review the operations permit application under proposed § 9.52, which states that the NPS will review the application under the same standards that apply to new operations, §§ 9.100 through 9.104 (Operations Permit: Application Review Process).

Under proposed § 9.53, from the effective date of the final rule and during the time a previously exempt operator’s application is under consideration for approval by the NPS, the continuation of operations would be

limited to those activities and the specific area of disturbance as of the effective date. Previously exempt operations would also become subject to the General Terms and Conditions at proposed §§ 9.120 through 9.122 and the Prohibitions and Penalties at proposed §§ 9.180 through 9.182. Finally, proposed § 9.53(a)(2) provides that except in an emergency, the NPS would not take any steps to directly regulate the previously exempt operator’s activities under proposed §§ 9.180 through 9.182 within 90 days after the effective date of the final rule.

Proposed rule	Existing regulation
§§ 9.60 through 9.63 <i>Temporary Access Permits.</i>	§ 9.38.

#### **§§ 9.60 Through 9.63—Temporary Access Permits**

Existing § 9.38(a)(2) (temporary approval for the continuance of existing operations) and existing § 9.38(b) (temporary approval of new operations) would not be retained in the proposed rule. Because the proposed rule would make all operations subject to the 9B regulations, including (after a 90-day grace period) previously exempt operations, temporary approval of existing operations is no longer applicable. Existing § 9.38(b) would also be deleted because the provision has rarely been used and the NPS does not anticipate a need for temporary approval of new operations.

Proposed § 9.60 would focus solely on the information requirements and approval process for obtaining temporary approval to collect basic information to develop the information required to obtain an Operations Permit. Proposed § 9.61 identifies the information necessary for the NPS to evaluate the operator’s proposal to collect this information. This includes intended future operations, so the NPS can determine what information is available and what additional information needs to be gathered. Proposed § 9.61(d) would require that the operator describe the qualifications of the specialist who will perform the reconnaissance survey. The requirement to hire a qualified specialist codifies existing NPS guidance and is included in the definition of “reconnaissance survey” so that information and conclusions are accurate and verifiable.

Proposed § 9.62 would clarify that under a Temporary Access Permit, an operator may not engage in ground disturbing activities unless they are minimal and necessary to conduct the surveys.

Under proposed § 9.63, Temporary Access Permits would be issued for a period not to exceed 60 days and may be extended for a reasonable additional period when justified by an operator.

Proposed rule	Existing regulation
§§ 9.70 through 9.73 <i>Accessing Oil and Gas Rights from a Surface Location Outside the Park Boundary.</i>	§ 9.32(e).

**§§ 9.70 Through 9.73—Accessing Oil and Gas Rights From a Surface Location Outside the Park Boundary**

Existing § 9.32(e) allows operators to apply for an exemption from the regulations if they directionally drill from a surface location outside an NPS unit to reach a bottom hole located within NPS boundaries. This exemption is available if operations pose no significant threat of damage to NPS resources, both surface and subsurface, resulting from surface subsidence, fracture of geological formations with resultant fresh water aquifer contamination, or natural gas escape. Surface activities located outside the NPS boundary are not within the scope of the existing 9B regulation. Under these regulations, regulatory authority over these operations continues to begin at the subsurface point where the proposed operation (borehole) crosses the park boundary and enters federally owned or controlled lands or water, and applies to all infrastructure and activities within the NPS unit.

The availability of the exemption provides an incentive for operators to locate surface facilities outside an NPS unit. Location of operations outside an NPS unit generally avoids direct impacts to NPS resources and values. Therefore, proposed § 9.72 retains a similar exemption.

The NPS proposes to retain the “no significant threat of damage” review standard for exemption applications. Proposed § 9.70 updates and clarifies the review standards for exemption applications. If an operator is exempt from the Operations Permit requirement, it would still be subject to the General Terms and Conditions and the Prohibitions and Penalties provisions in the regulations. The proposed rule also addresses circumstances under which the method of operation or environmental conditions of an operation changes.

Proposed § 9.71 identifies the information an operator would be required to submit to the NPS to be considered for an exemption. Proposed

§ 9.71 directs operators to those information requirements, located at proposed § 9.89, applicable to proposed hydraulic fracturing operations.

Proposed § 9.72 describes how the NPS would review and consider information submitted by the operator under this section.

Proposed § 9.73 describes requirements that an operator still must meet if it does not need an operations permit.

Proposed rule	Existing regulation
§§ 9.80 through 9.90 <i>Operations Permit: Application Contents.</i>	§ 9.36. § 9.42.

**§§ 9.80 Through 9.90—Operations Permit: Application Contents**

*Format*

The proposed rule at §§ 9.80 through 9.90 reorganizes information requirements for each type of operation. The proposed rule would separate information requirements into the following categories: § 9.83, information that must be included in all applications; § 9.87, additional information that must be included for a proposed geophysical exploration; § 9.88, additional information that must be included for a proposed drilling operations; § 9.89 additional information must be included for a proposed well stimulation operations, including hydraulic fracturing; and, § 9.90 additional information that must be included for a proposed production operations.

*Additions to and Clarification of Existing Information Requirements*

Some of the information requirements in the existing 9B regulation are minimally described. The NPS provided additional information on some of those information requirements in the NPS’s 2006 9B Operator’s Handbook. The NPS intends to clarify all information requirements in the proposed rule.

*Information Requirements That Apply to All Operations Permit Applications*

Some of the existing information requirements were incorporated into the proposed rule without substantial change. However, the NPS is proposing to clarify the following information requirements:

*Ownership Information*

Existing regulation § 9.83 limits identification of an operation’s key personnel to the operator, owners, and lessees. To ensure that the NPS has all appropriate contact information,

proposed § 9.83(b) requires that operators also identify agents, assignees, designees, contractors, and other representatives.

- *New Surface Disturbance and Construction*

Proposed § 9.84 requires an operator to specify site security measures and an operation’s power sources and transmission systems.

- *Use of Water*

Proposed § 9.83(e) would clarify and expand upon the existing § 9.36(a)(5). It would require information regarding the source, transportation method and quantity of water to be used in addition to how the operator will manage waste water.

- *Environmental Conditions and Mitigation Actions*

Proposed § 9.85 would codify the existing practice of requiring operators to include within their permit application natural resource and cultural resource survey reports for the operator’s proposed area of operations.

Proposed § 9.85 would require an operator to describe steps proposed to mitigate adverse environmental impacts and list and discuss the impacts that cannot be mitigated. Additionally, operators are required to describe all alternative technologically feasible, least damaging methods that were considered. Technologically feasible, least damaging alternatives are those alternatives that are viable (based on economic, environmental, and technological considerations) and conform to federal, state, and local laws and regulations.

- *Cultural Resources*

The NPS proposes to eliminate existing § 9.47(a), “Cultural Resource Protection,” because the section merely summarizes the requirements of the Antiquities Act (54 U.S.C. 320301 *et seq.*). Restating these statutory requirements in the 9B Regulations is unnecessary, and the section also fails to acknowledge other statutes that could also apply to these resources.

- *Spill Control and Emergency Preparedness Plan*

Proposed § 9.86 consolidates various sections of the existing regulation, clarifies that an operator must submit a Spill Control and Emergency Preparedness Plan (SCEPP) plan to the NPS, and identifies the information necessary to complete a SCEPP.

*Additional Information Requirements That Apply to Geophysical Operations*

Proposed § 9.87 clarifies the additional information a geophysical operator would need to submit to the NPS.

### *Additional Information Requirements That Apply to Drilling, Stimulation, and Production*

Proposed §§ 9.88 through 9.90 clarify the additional information an operator would need if it is proposing to drill, stimulate, or produce a well.

Proposed § 9.89 is a new set of information requirements for well stimulation, including hydraulic fracturing operations. Information requirements include identifying the geologic barriers between the target zone and the deepest usable water zone, verifying mechanical integrity of the wellbore, and describing water use and disposal management of flowback fluids. NPS notes that the Bureau of Land Management (BLM) has recently promulgated regulations addressing hydraulic fracturing on federal and Indian lands at 43 CFR part 3160 (80 FR 16128, March 26, 2015). We have carefully considered the BLM regulations to ensure that the NPS regulations are as consistent as possible. Here, the NPS proposed rule uses most of the language from BLM's hydraulic fracturing information requirements at 43 CFR 3162.3–3(d)(1) through (7). Where a BLM information requirement is not specifically included in proposed § 9.89, it is because NPS already has equivalent information requirements that are applicable to all operations. Additionally, NPS has specific guidance on the means to ensure well integrity standards are met in its NPS's 2006 9B Operator's Handbook.

Proposed rule	Existing regulation
§§ 9.100 through 9.105 Operations Permit: Application Review Process.	§ 9.37. § 9.48.

### **§§ 9.100 Through 9.105—Operations Permit: Application Review Process**

Existing § 9.37(a)(1) requires that, before approving a plan of operations, the Regional Director determine that the operator uses technologically feasible, least damaging methods that provide for protection of the park's resources and public health and safety.

The existing rule has two different approval standards, depending on whether the operation is proposed on non-federally or federally owned surface. For operations proposed on non-federally owned surface a Regional Director cannot approve an operation that would constitute a nuisance to federal lands or waters in the vicinity of the operations, or would significantly injure federally owned or controlled lands or waters. For more information

on what would constitute "significantly injure" please see *NPS Procedures Governing Nonfederal Oil and Gas (1992)*, pages 30–31, which can be found at <http://parkplanning.nps.gov/documentsList.cfm?projectID=28329>. For operations proposed on federally owned surface a Regional Director cannot approve an operation that would substantially interfere with management of the unit to ensure the preservation of its natural and ecological integrity in perpetuity, or would significantly injure federally owned or controlled lands or waters. If applying the standard for operations proposed on federally owned lands would constitute a taking of a property interest, the NPS may either approve the operations if it uses technologically feasible, least damaging methods or acquire the mineral interest.

Existing § 9.37(b) and (c) require the NPS to make a decision on the plan of operations within 60 days after the date that the NPS determines that the materials submitted under the plan are adequate. Within 60 days, the Regional Director must make one of six final decisions in writing. The final decisions are: Approval or rejection; conditional approval; modification to the plan or additional information is required; more time is necessary to complete review; environmental statement is required before approval; or more time is necessary for public participation and analysis of public comments.

Existing § 9.37(c) provides that failure of the NPS to make a final decision within 60 days constitutes a rejection of the plan. The operator has a right to appeal this decision under existing § 9.49.

#### *Proposed Application Review Process*

The proposed rule establishes a two-stage permit application review process, eliminates the dual approval standards, provides more realistic timeframes to provide notice back to an operator, and consolidates the final decisions the NPS can make on an operator's permit application.

#### *Stage One: Initial Review*

Proposed § 9.101 describes the NPS's initial review of an operator's permit application. During initial review the NPS would determine whether the applicant has supplied all information necessary for the NPS to evaluate the operation's potential effects affecting federally owned or administered lands, waters, or resources of NPS units, visitor uses or experiences, or visitor or employee health and safety. The NPS would respond to applicants within 30 days and tell them whether the information contained in their permit

applications is complete. If the NPS needs more time to complete the review, the NPS will provide the applicant with an estimate of the amount of additional time reasonably needed and an explanation for the delay. Once a permit application is complete the NPS conducts formal review.

#### *Stage Two: Formal Review*

During formal review under proposed § 9.102 the NPS evaluates whether the proposed operation meets the NPS approval standards (§ 9.103) and conducts its compliance responsibilities under applicable federal statutes (*e.g.* National Environmental Policy Act (NEPA), Endangered Species Act (ESA), and National Historic Preservation Act (NHPA)).

#### *Timeframe for Final Action*

In light of NPS experience over the past 35 years in implementing the 9B regulations, the current 60-day period for reaching a final decision on a permit application is not realistic. These decisions require time to adequately analyze an operator's proposal, work with the operator on a design that incorporates acceptable avoidance and mitigation measures, and comply with the associated federal statutory responsibilities such as NEPA, ESA, and NHPA. The regulations should provide operators with realistic expectations of the timeframe to process operations permits in order to adequately plan for the start of operations. Similarly, the NPS must take into account realistic timeframes for its coordination with other federal and state agencies. Thus, proposed § 9.104 allows the NPS 180 days to complete its formal review. The proposed regulation would allow for a longer period of time, if the parties agree to it, or if the NPS determines that it needs more time to comply with applicable laws, executive orders, and regulations. In some cases, the NPS may be able to complete formal review in less than 180 days. The NPS is seeking comment on whether 180 days is reasonable and any incremental impacts on operators.

The proposed rule would remove existing section § 9.37(c), which results in a rejection of the proposal if the NPS does not respond within 60 days, and replaces it with § 9.104, which authorizes the Superintendent to notify the operator in writing that additional time is necessary to make a final decision.

#### *Elimination of Dual Approval Standards*

Proposed § 9.103 would replace the existing dual approval standards with a single three-part approval standard that

applies to all operations, regardless of surface ownership. Oil and gas operations located on non-federally owned surface have the potential to impact federally owned or administered lands, waters, or resources of NPS units, visitor uses or experiences, or visitor or employee health and safety to the same degree as operations sited on federally owned surface.

Proposed § 9.103(a) lists three basic determinations that the Regional Director must make before approving an application for an operations permit.

Proposed § 9.103(b) adds two other prerequisites to approval: (1) Submittal of adequate financial assurance and (2) proof of adequate liability insurance.

*Final Actions*

Proposed § 9.104 would establish two final actions: (1) Approved, with or without conditions, or (2) denial, and the justification for the denial. The Regional Director would notify the operator in writing of the final action. If approved, this written notification constitutes the NPS’s authorization to conduct activities.

The NPS has eliminated the proviso in the approval standard in current section § 9.37(a)(3), which allows for approval using only the “technologically feasible, least damaging methods” standard of section § 9.37(a)(1) if application of the more stringent § 9.37(a)(3) standard would constitute a taking of a property interest. Over the past 35 years of implementing the 9B Regulations, the NPS has never used this exception. In every instance, the NPS has authorized operators’ access and protected park resources and values by applying reasonable avoidance and mitigation measures to the exercise of operators’ mineral rights. As noted in the Purpose and Scope section above, the proposed rule at § 9.30(c) maintains the existing regulatory provision stating that the 9B regulations are not intended to result in a taking of mineral rights. The approval standard in the proposed rule simply incorporates that provision by reference, rather than expressly spelling it out as part of the standard. This change is not intended or expected to authorize any taking of property rights, and is intended solely to simplify the approval standards and avoid redundancy and confusion. The NPS will continue to work with operators to help plan and design their operations in a way that meets NPS operating standards and other applicable provisions of these regulations.

*Compliance With Big Cypress National Preserve Addition Act*

The Big Cypress National Preserve Addition Act (BCNPAA), (16 U.S.C. 698m–4), requires that the NPS include language describing the procedures for reviewing an Operations Permit application within the Big Cypress National Preserve and Addition Area.

Accordingly, proposed § 9.105 describes the procedure for initial review of a proposed operation in Big Cypress National Preserve. This procedure would differ slightly from the service-wide procedure described in §§ 9.101 and 9.102. The NPS’s service-wide proposed rule incorporates the 30-day initial review period from the BCNPAA. However, the BCNPAA at 16 U.S.C. 698m–4(b)(2)(C) places a regulatory limit on the amount of collaboration that can occur between the NPS and the operator. Under this provision, there is no regulatory mechanism for the NPS to request further information from an operator after the NPS has made its initial request for additional information. After making such a request, the NPS’s only options are to approve or deny the application. This procedure could conceivably result in denial of applications that would have been approved if the NPS had the regulatory authority to again request the additional information necessary to fully evaluate a proposed operation. In practice, the NPS will continue to collaborate with prospective operators in Big Cypress National Preserve early in their planning process and as much as possible during initial review, in order to reduce such theoretical problems. The NPS is not proposing to use the Big Cypress procedure in its service-wide regulations, because it does not want to constrain its ability to have more robust collaboration with operators.

The BCNPAA also differs slightly from the proposed service-wide rule in that under the BCNPAA the 90-day time period for final action begins upon submission of the permit application to the NPS. For the service-wide rule, the NPS has chosen not to adopt submission of the permit application as the triggering event for the 180-day time period. Rather, the NPS proposed service-wide rule provides that the 180-day time period begins upon the NPS determination that the operator’s permit application contains complete information. This is consistent with the existing 9B Regulations at 36 CFR 9.36(c). Before the NPS can begin to conduct an analysis of an operator’s proposal, it must have all necessary information from an operator. For

proposals within Big Cypress National Preserve, the NPS will strive to meet the applicable timeframe for final action while otherwise complying with applicable laws including NEPA and the ESA.

The NPS has decided to include applicable language from the BCNPAA in this regulation instead of in a new park-specific regulation in Part 7, because the remaining sections of the 9B regulation still apply to oil and gas operations in Big Cypress National Preserve and the NPS believes it will be easier for operators to have all applicable regulations in one place.

Proposed rule	Existing regulation
§§ 9.110 through 9.118 Operating Standards.	§ 9.35.
	§ 9.39.
	§ 9.41.
	§ 9.42.
	§ 9.43.
	§ 9.44.
	§ 9.45.
	§ 9.46.
	§ 9.47.

**§§ 9.110 Through 9.118—Operating Standards**

*Purpose and Function*

Proposed § 9.110 clarifies the purpose and function of operating standards. The NPS would maintain the current practice of setting non-prescriptive operating standards to allow operators the flexibility to design their proposed operation using the latest technological innovations that will best protect park system resources, values, and visitor health and safety.

Proposed § 9.110(c) is a general standard that requires all operators to use technologically feasible, least damaging methods to protect NPS resources and values while assuring human health and safety.

Proposed § 9.110(a) maintains the practice of incorporating applicable operating standards into an approved operations permit so that the operating standards become enforceable terms and conditions of an approved permit.

The existing regulation has a specific operating standards provision at § 9.41. Additional operating standards are scattered throughout other sections of the existing regulations (See, §§ 9.43 through 9.46).

*Reorganization*

The proposed rule would reorganize operating standards into one section and separate operating standards into the following categories: §§ 9.111 through 9.116, are operating standards that apply to all operations; § 9.117, additional operating standards that

apply to geophysical operations; and § 9.118, additional operating standards that apply to drilling, stimulation, and production operations. The NPS believes that organizing the standards in this manner would allow the NPS and the operator to readily understand which operating standards are applicable to the particular type of proposed operation.

#### *Additions to and Clarification of Existing Operating Standards*

Some of the operating standards in the existing 9B regulation are minimally described. The NPS has clarified some operating standards in its 2006 9B Operator's Handbook. The NPS proposes to include all operating standards in the proposed rule. The NPS would incorporate some operating standards from the existing regulations into the proposed rule largely without substantive change; those standards are not further discussed here. The standards summarized below either clarify existing standards or are new standards that the NPS proposes to add to the regulations.

#### *Operating Standards That Apply to All Operations*

The NPS is proposing to include new standards at § 9.111(a) to ensure that either existing or newly created surface disturbance is kept to the minimum necessary for safe conduct of operations.

The NPS is proposing to include new standards at § 9.114 and § 9.115 that would reasonably limit the visual and sound impacts of oil and gas operations on park visitor use and experience.

The NPS is proposing to add a new standard at § 9.111(h) that would avoid or limit the introduction of exotic species.

The NPS is proposing to add specific standards at § 9.112 that would address hydrologic connectivity.

#### *Reclamation Operating Standards*

Proposed § 9.116 would specify reclamation operating standards.

#### *Operating Standards That Apply to Geophysical Operations*

Proposed § 9.117 covers operating standards for surveying methods; source points; use of equipment and methods; and shot holes.

#### *Operating Standards That Apply to Drilling, Stimulation, and Production Operations*

Proposed § 9.118(a)(1) requires all operators to use containerized mud systems during drilling operations.

Proposed § 9.118(a)(2) prohibits the establishment of new earthen pits for

any use. Use of existing earthen pits may continue if the pits are in compliance with applicable law and subject to the Superintendent's periodic inspection.

Proposed § 9.118(b) is a new section that establishes standards for well stimulation, including standards that address hydraulic fracturing operations, such as ensuring the mechanical integrity of the wellbore, water use and disposal, and management of flowback fluids. We have carefully considered the recently promulgated BLM oil and gas regulations to ensure that the NPS regulations are as consistent as possible. The two agencies take different approaches to operating standards, though, because of their differing statutory bases for regulating the exercise of oil and gas rights. BLM's regulatory authority is derived primarily from the Mineral Leasing Act and the Federal Land Policy and Management Act and controls the use of federal property. The NPS 9B regulations address private property rights within park units and are based largely on the directive of the NPS Organic Act to "conserve the scenery, natural and historic objects, and wild life in the System units and to provide for the enjoyment of the scenery, natural and historic objects, and wild life in such manner and by such means as will leave them unimpaired for the enjoyment of future generations." As a result, BLM can and has appropriately set more prescriptive standards in its regulation, while NPS has generally set required non-prescriptive operating standards which allow operators flexibility to design operations while still protecting park system resources, values, and visitor health and safety. For example, BLM's regulation at 43 CFR 3162.5-2 (Control of wells) sets a performance standard with regard to protection of usable water, and BLM also prescribes regulatory measures necessary to achieve and verify the performance standard (43 CFR 3162.3-3(e)). NPS's approach is to review an operator's submissions to determine if they meet the overall operating standard of using the most "technologically feasible, least damaging methods" that protect park resources and values, and all other applicable operation standards. If not, the NPS would add terms and conditions in the permits to ensure that they do so. Guidance on the specific means to meet NPS operating standards is found in NPS's 2006 9B Operator's Handbook, which is distributed to every operator and available electronically.

Proposed rule	Existing regulation
§§ 9.120 through 9.122 <i>General Terms and Conditions</i> .	§ 9.35. § 9.36(a)(15). § 9.37(f). § 9.41(g). § 9.42. § 9.46. § 9.51(b).

#### **§§ 9.120 Through 9.122—General Terms and Conditions**

The NPS proposes a new "General Terms and Conditions" section to summarize those terms and conditions that apply to all operations. This section consolidates existing: §§ 9.35; 9.36(a)(15); 9.37(f); 9.41(g); 9.42; 9.46; 9.47(b); and, 9.51(a) and (b).

The water use section at existing § 9.35 does not address all state water law systems under which water rights are established or decided. Proposed § 9.120(b) would require that the NPS approve, in accordance with NPS policy, the use of surface or groundwater owned or administered by the United States.

Because monitoring and reporting requirements apply, in varying degrees, to all operations, the NPS is proposing to include monitoring and reporting requirements under General Terms and Conditions. Some of these monitoring and reporting requirements are taken from the existing regulation while others are new requirements. The new requirements are described below.

Proposed § 9.121(b) would allow the NPS to require that operators hire third party monitors when they are necessary to ensure compliance and protect park resources and values. The NPS currently requires the use of third party monitors to help the NPS ensure that it receives unbiased, reliable, and timely monitoring information demonstrating an operator's compliance with its plan of operations. See, 2006 9B Operator's Handbook, Chapter 3 (Geophysical Exploration). Over the past fifteen years, Big Thicket National Preserve, Padre Island National Seashore, Jean Lafitte National Historic Site, and Big Cypress National Preserve have required operators to use third party monitors for geographically extensive and logistically complex 3D seismic operations. The use of third party monitors has allowed the NPS to augment monitoring by park staff so that the operator can simultaneously engage in multiple operations at different locations, while still ensuring compliance with the operator's plan. The proposed rule would also make the NPS's requirements more consistent with the practice of other federal agencies (BLM, the U.S. Forest Service, and the U.S.

Fish and Wildlife Service have all required third party monitoring for oil and gas operations on lands they administer), as well as state oil and gas regulatory agencies. This section describes the criteria that the NPS will consider when making the decision to require a third party monitor. The third party monitor would report directly to the NPS to ensure oversight and accountability.

Proposed § 9.121(e) would broaden the reporting requirement to require that the operator submit any information requested by the Superintendent that is necessary to verify compliance with either a provision of the operations permit or this subpart. To ease this burden the proposed rule would allow an operator to submit reports that the operator has already submitted to a state or other federal agency to meet this reporting requirement, similar to existing § 9.42.

Proposed § 9.122 would require reporting related to the hydraulic fracturing process, including the disclosure of chemicals used in the hydraulic fracturing process and the volume of recovered fluids. In § 9.122, NPS has used BLM's post-hydraulic fracturing reporting requirements, but did not include two provisions (requirement for affidavit of compliance and general supporting documentation), as these requirements are addressed in other sections of this proposed rule.

Proposed rule	Existing regulation
§§ 9.130 through 9.132 <i>Access to Oil and Gas Rights.</i>	§ 9.50.

**§§ 9.130 Through 9.132—Access to Oil and Gas Rights**

Existing § 9.50 authorizes the NPS to charge a fee for commercial vehicles using NPS administered roads.

Proposed 9.130(b) would clarify that adequate and feasible access to oil and gas rights located within the boundaries of NPS units in Alaska is governed by the regulations at 43 CFR part 36, which implements § 1110(b).

Proposed § 9.131(a)(1) would supplement that authority to allow a fee based on fair market value for access (e.g., roads or gatherings lines) across federal lands outside the scope of an operator's oil and gas right. The NPS would set fees consistent with NPS Part 14 Rights-of-way guidance (NPS Reference Manual 53, Special Park Uses, Appendix 5, Exhibit 2).

The NPS is seeking public comment on whether the NPS should include a provision that would allow the NPS to authorize an operator to undertake

compensatory mitigation in lieu of payment. The value of the compensatory mitigation would be proportional to the reasonable estimated cost of the access fee. This would allow the operator and the NPS to agree on an option to, for example, reclaim an area of previously disturbed land elsewhere within the park to offset the operator's new access.

Proposed rule	Existing regulation
§§ 9.140 through 9.144 <i>Financial Assurance.</i>	§ 9.48.

**§§ 9.140 Through 9.144—Financial Assurance**

The NPS proposes to rename the "Performance Bond" section as "Financial Assurance" to reflect the variety of instruments that an operator can provide to the NPS to meet its obligation under this section.

Existing § 9.48(a) requires an operator to file a performance bond, or other acceptable method of financial assurance, for all types of non-federal oil and gas operations and all phases of the operations. The performance bond requirement ensures that in the event an operator becomes insolvent or defaults on its obligations under an approved plan of operations, adequate funds will be available for reclamation.

Existing § 9.48(d)(3) limits the performance bond amount to \$200,000 per operator, per NPS unit. Therefore, if one operator has multiple wells in an NPS unit, the NPS can only require up to \$200,000 financial assurance from that operator. The existing \$200,000 limit was established in 1979 and in most cases no longer represents the current potential costs of reclamation. In the event of a default by the operator, reclamation costs exceeding the limit could require the NPS to bring a civil action in federal court to recover the additional costs.

Proposed § 9.141 would make the financial assurance amount equal to the estimated cost of reclamation. This revision would substantially reduce the risk of the American taxpayers being left to assume the operator's reclamation-responsibility costs if an operator defaults on its obligations.

Proposed § 9.142 outlines the process for adjusting the amount of financial assurance due to changed conditions. Proposed § 9.143 describes the conditions under which the NPS would release the financial assurance. Proposed § 9.144 describes those circumstances that would result in forfeiture.

Proposed § 9.144(b)(3) is a new provision allowing the NPS to suspend review of an operator's pending permit applications, if that operator has forfeited its financial assurance. Suspension would last until the Superintendent determines that all violations have been resolved.

Proposed rule	Existing regulation
§§ 9.150— <i>Modification to an Operation.</i>	§ 9.40.

**§ 9.150—Modification to an Operation**

Proposed § 9.150, would rename the "Supplementation or Revision of Plan of Operations" section as "Modification to an Operation" to characterize any change to an approved operations permit. This section would clarify that either the NPS or the operator can request modification of the operator's permit, and describes the modification procedures. Approval of any modification to an approved permit must meet the same criteria that apply to Temporary Access Permits (proposed §§ 9.60 through 9.63) or Operations Permit: Application Review Process (proposed §§ 9.100 through 9.105).

Proposed § 9.150(c) would prohibit an operator from implementing a modification until the NPS has provided written approval of the modification to the operator.

Proposed rule	Existing regulation
§§ 9.160 and 9.161 <i>Change of Operator.</i>	§ 9.34.

**§§ 9.160 and 9.161—Change of Operator**

This proposed section renames the existing § 9.34 "Transfer of Interest" section as "Change of Operator."

Existing § 9.34(a) provides that a previous owner remains liable on its financial assurance until it informs the NPS that the rights have been transferred to another party. A new owner cannot operate until it posts financial assurance and ratifies the existing plan of operations. If the previous owner provides notice to the Superintendent, the previous owner could request release of its financial assurance before the new owner posts its own financial assurance with the NPS. Therefore, if the new owner abandons operations before posting financial assurance with the NPS, the burden of reclaiming the site could fall on the taxpayers.

Proposed § 9.160 holds the previous operator responsible to the NPS until



the new operator adopts and agrees to the terms and conditions of the previous operator's permit and provides financial assurance. Proposed § 9.160(a) addresses a transfer of operation where the previous operator did not have an approved NPS permit. Proposed § 9.160(b) requires the previous operator to notify the NPS of its transfer.

Proposed § 9.161 requires that the new operator adopts and agrees to the terms and conditions of any previous operator's operations permit. Proposed § 9.161(b) addresses transfer of an operation where an exemption was previously granted under proposed § 9.72.

Proposed rule	Existing regulation
§§ 9.170 and 9.171 <i>Well Plugging.</i>	§ 9.39.

**§§ 9.170 and 9.171—Well Plugging**

This section replaces, in part, existing § 9.39(a)(2)(iv) and creates a new section "Well Plugging."

Existing § 9.39(a)(2)(iv) requires operators to plug and cap all non-productive wells and to fill dump holes, ditches, reserve pits, and other excavations. Proposed § 9.116(d)(1) (Operating Standards) would retain the requirement that an operator conduct reclamation by plugging all wells. However, the existing regulations do not give the NPS the authority to require an operator to plug wells that have been in extended shut-in status. As a result inactive wells have remained unplugged for years and, in some instances, decades. Unplugged wells could adversely impact park resources and could also present risks to park visitors.

Proposed § 9.170(a) would establish that operators are required to plug a well within a specified time period after cessation of drilling or production operations or upon the expiration of NPS approved shut-in status. Under proposed § 9.171, an operator can seek an extension to the plugging requirement if the operator describes why drilling or production operations have ceased and its reasonable future use of the well, demonstrates mechanical integrity, and follows maintenance requirements.

The proposed procedures are consistent with the way many states approach the issue of inactive wells, and recognize that certain economical or logistical reasons exist to justify maintenance of wells in shut-in status for extended periods of time. Rather than a "produce or plug" policy, the proposed regulation provides assurance that shut-in wells are maintained in an

environmentally sound and safe manner.

Proposed rule	Existing regulation
§§ 9.180 through 9.182 <i>Prohibitions and Penalties.</i>	§ 9.48(e). § 9.51.

**§§ 9.180 Through 9.182—Prohibitions and Penalties**

Existing § 9.51(c) provides two different compliance procedures for suspending an operation, depending on whether or not the violation poses an "immediate threat of significant injury to federally owned lands or waters." Proposed § 9.181 would allow the Superintendent discretion to suspend an operation regardless of whether an operator's violation poses an "immediate threat of significant injury." Whether the threat is immediate or not, any violation that results in a threat of damage to park resources and values should be addressed by the Superintendent.

*Prohibited Acts*

Proposed § 9.180 lists the prohibited acts to provide operators with notice of the acts that would constitute a violation of the 9B regulations. The proposed rule expands the prohibited acts to include not only violation of the terms and conditions of an Operations Permit, but also violations of other provisions of the 9B regulations.

*Incorporating Existing 36 CFR 1.3 Penalties Provision in the 9B Regulations*

Existing § 9.51 authorizes the NPS to suspend an operation for non-compliance and if the violation or damage is not corrected, revoke an operator's plan of operations. The process to suspend an operation requires coordination between park staff and other NPS offices during which time damage to park system resources and values may continue. Additionally, suspension and revocation are not necessarily the most appropriate means to correct minor acts of non-compliance (minor leaks and spills, improper road maintenance, or not maintaining proper site security). Therefore, we are proposing to incorporate our existing penalties at 36 CFR 1.3 that would allow NPS law enforcement rangers and special agents to issue citations, which would result only in fines for minor acts of non-compliance, while treating the more serious acts as ones that may be subject to a fine or imprisonment, or both.

*No New Authorization Unless Operator Is in Compliance*

Under proposed § 9.182 NPS would not review any new operating permit applications or continue to review any pending permit applications anywhere in the National Park System until an operator comes into compliance with a violation of this subpart or a violation of a term or condition of an operations permit.

Proposed rule	Existing regulation
§§ 9.190 through 9.194 <i>Reconsideration and Appeals.</i>	§ 9.49.

**§§ 9.190 Through § 9.194—Reconsideration and Appeals**

Most of the procedures outlined in existing § 9.49 remain the same. The operator continues to have the right to appeal a decision made by either the Superintendent or the Regional Director. The operator now must exhaust these remedies before the NPS decision is considered a final agency action that is subject to review under the Administrative Procedure Act (APA).

The proposed rule now describes the first step of the process as a request for "reconsideration," rather than an appeal, since it is directed to the same official who issued the original decision. The proposed rule also includes other clarifications of the existing language, makes editorial corrections, and reorganizes the sequence of some of the paragraphs.

Consistent with the APA, proposed § 9.193(a) would provide that during the reconsideration and appeals process the NPS's decision will be suspended and the decision will not become effective until the completion of the appeals process. Proposed § 9.193(b) addresses suspension of operations due to emergencies that pose an immediate threat of injury to injury to federally owned or controlled lands or waters.

Proposed rule	Existing regulation
§ 9.200 <i>Public Participation.</i>	§ 9.52.

**§ 9.200—Public Participation**

The proposed rule renames the "Public Inspection of Documents" section to "Public Participation."

Existing § 9.52(a) requires a Superintendent to publish a notice in a local newspaper of a request to conduct non-federal oil and gas operations whether or not a complete plan of operations is ever submitted by an



operator. Existing § 9.52(b) further requires a Superintendent to publish a notice in the **Federal Register** of receipt of a plan of operations. The proposed rule eliminates the public notice steps currently required under existing § 9.52(a) and (b) and replaces them with a more efficient public involvement and review process.

The proposed rule retains the ability for an operator to protect proprietary or confidential information from disclosure to the public. Operators need to clearly mark those documents that they wish to protect from public disclosure as “proprietary or confidential information” such that these documents are readily identifiable by the NPS decision maker. The NPS has also included proposed provisions that allow an operator engaged in hydraulic fracturing operations to withhold chemical formulations that are deemed to be a trade secret.

Proposed rule	Existing regulation
§ 9.210 <i>Information Collection.</i>	<i>New Section.</i>

**§ 9.210—Information Collection**

See Paperwork Reduction Act discussion below.

**Renumbering and Redesignation of Subpart D**

As a result of the new organization and section numbering in the proposed subpart B, it is necessary to renumber the sections in the existing part 9, subpart D. In addition, because we see no reason to continue to reserve subpart C, the proposed rule redesignates the existing subpart D as subpart C. The proposed rule makes no substantive changes to these provisions.

**Compliance With Other Laws, Executive Orders, and Department Policies—Regulatory Planning and Review (Executive Orders 12866 and 13563)**

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this proposed rule is significant because it may raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive order.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative,

and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this proposed rule in a manner consistent with these requirements. As noted above, we have carefully considered the BLM regulations to ensure consistency to the greatest extent possible between provisions of these proposed NPS regulations that relate to hydraulic fracturing, and the recent BLM regulations. The NPS is aware of the current litigation concerning BLM’s final hydraulic fracturing rule, *State of Wyoming v. U.S. Department of the Interior*, Case No: 2:15–CV–043–SWS, and will consider public comment as well as any rulings that may occur in the litigation in reaching final decisions on its final rule.

**Regulatory Flexibility Act (RFA)**

This rule would not have a significant economic effect on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This certification is based on the cost-benefit and regulatory flexibility analysis found in the report *Cost-Benefit and Regulatory Flexibility Analyses: U.S. Department of the Interior, National Park Service for Proposed Revisions to 36 CFR Part 9, Subpart B* which can be viewed at [http://www.nature.nps.gov/geology/oil\\_and\\_gas/9b\\_index.cfm](http://www.nature.nps.gov/geology/oil_and_gas/9b_index.cfm).

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

This proposed rule is not a major rule under 5 U.S.C. 804(2) of the SBREFA. This proposed rule:

- (a) Does not have an annual effect on the economy of \$100 million or more;
- (b) Would not cause a major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regions; and
- (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

These conclusions are based upon the cost-benefit and regulatory flexibility analysis found in the report entitled *Cost-Benefit and Regulatory Flexibility*

*Analyses: U.S. Department of the Interior, National Park Service for Proposed Revisions to 36 CFR Part 9, Subpart B* which can be viewed at [http://www.nature.nps.gov/geology/oil\\_and\\_gas/9b\\_index.cfm](http://www.nature.nps.gov/geology/oil_and_gas/9b_index.cfm).

**Unfunded Mandates Reform Act (UMRA)**

This proposed rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year. The proposed rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. It addresses use of national park lands, and imposes no requirements on other agencies or governments. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

**Takings (Executive Order 12630)**

The proposed rule does not take private property or authorize the taking of private property. Moreover, NPS believes that implementation of the proposed rule is not likely to result in a taking of private property. Accordingly, NPS believes that the proposed rule does not require the preparation of a takings implications assessment under Executive Order 12630.

The proposed rule would update regulations that have been in effect since 1979. It would update various provisions of the existing regulations in a manner that is consistent with current industry standards and technological capabilities, prevailing industry and investor expectations, and the most recent developments in regulatory and takings law. It would authorize NPS to recover its legitimate permit-processing and monitoring costs and to charge operators for privileged access across federal lands (*i.e.*, access that is not a legal right incident to the mineral estate). Although it would potentially increase the amount of financial assurance that operators must post, it would do so only to a level commensurate with the cost of restoring the federally owned surface estate.

The proposed rule would extend the applicability of the 9B regulations to most currently exempt operations located within park boundaries. During the 36 years that the existing regulations have been in place, however, NPS has never disapproved a submitted plan of operations and no mineral owner or operator has ever filed a claim asserting that implementation of the regulations has resulted in a taking of private property. Moreover, as described above, the proposed rule would update the

existing regulations in a manner consistent with current industry standards and technological capabilities. Accordingly, NPS does not believe that the application of the proposed rule to currently exempt operations is likely to result in a taking. The proposed rule would continue to allow operators reasonable access across federally owned surface to develop non-federal mineral rights. No other private property is affected. The proposed rule would bring outdated provisions into line with modern regulatory practice and, NPS believes, is a reasonable exercise of its regulatory authority.

Finally, the regulatory text will continue to state (as do the existing regulations) that it is not intended to result in a taking. The existing regulations also contain a second provision that expressly applies the lower of the two standards of review in the event of a possible taking. Because the proposed rule would contain only one standard of review (in an effort to simplify the rule), such a provision no longer appears appropriate. NPS has never actually needed to invoke that second provision, nor has it ever failed to provide final approval for a plan of operations that has been sought. Under the proposed rule, NPS would retain discretion to make individual permit decisions that will avoid a taking if an unexpected problem should arise.

For the foregoing reasons, NPS believes that a takings implications assessment is not required.

#### **Federalism (Executive Order 13132)**

Under the criteria in section 1 of Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. It addresses use of national park lands, and imposes no requirements on other agencies or governments. A Federalism summary impact statement is not required.

#### **Civil Justice Reform (Executive Order 12988)**

This proposed rule complies with the requirements of Executive Order 12988. Specifically, this rule:

- (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and
- (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

#### **Consultation With Indian Tribes (Executive Order 13175 and Department Policy)**

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's tribal consultation policy is not required. Nonetheless, NPS has consulted with all federal tribes traditionally associated with Category 1 parks, which have current oil and gas operations, and Category 2 parks, which do not have active operations, but have potential for future operations.

#### **Paperwork Reduction Act of 1995 (PRA)**

This proposed rule contains information collection requirements that we are submitting to the Office of Management and Budget (OMB) for review and approval under the PRA (44 U.S.C. 3501 *et seq.*). We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

OMB has reviewed and approved the current information collection requirements associated with non-Federal oil and gas rights in national parks and assigned OMB Control Number 1024-0064, which expires March 31, 2016. We are asking OMB to assign a new OMB Control Number for the information collection requirements in this proposed rule. If OMB approves this request, we plan to keep the new number for subpart B requirements after we publish the final rule. We will delete the burden associated with subpart B from OMB Control No. 1024-0064.

We are proposing to collect the following information under 36 CFR Part 9, Subpart B associated with non-Federal oil and gas operations within units of the National Park System.

#### **Previously Exempt Operations (§§ 9.50 Through 9.53)**

Previously exempt operators must submit the following information to the NPS:

- Brief description of the current operations and any anticipated changes to the current operations.
- Documentation showing the right to operate within an NPS unit.

- State well identification permit number or American Petroleum Institute (API) well number.
- Maps delineating the area of operations and the area of surface disturbance and equipment layout within the area of operations.
- Spill Control Environmental Preparedness Plan.
- Documentation of the current operating methods, surface equipment, downhole well construction and completion, materials produced or used, and monitoring methods.
- Description of how the operation will meet NPS operating standards.
- Description of procedures to be used and cost estimates for well plugging and surface reclamation.
- Results of any necessary reconnaissance surveys.

#### **Temporary Access Permits (9.60 Through 9.63)**

##### *Application for Temporary Access Permit*

To gather necessary background information for an Operations Permit, the operator will need to obtain a Temporary Access permit by submitting the following information to the NPS:

- Brief description of the intended future operation.
- Demonstration of the right to operate.
- Contact information for the person responsible for the overall management of the proposed operations.
- Contact information and qualifications of all specialists responsible for conducting the reconnaissance surveys.
- Map delineating the proposed reconnaissance survey area.
- Description of proposed means of access and routes to the survey area; and a description of the survey methods.

##### *Extension of Temporary Access Permit*

To extend the term of a Temporary Access Permit, operators must submit a written request that explains why the extension is necessary.

#### **Accessing Oil and Gas Rights From a Surface Location Outside the Park Boundary (9.70 Through 9.73)**

##### *Application for Exemption*

This proposed rule allows operators to apply for an exemption from the operations permit requirement of the regulations if they directionally drill from a surface location outside an NPS unit to reach a bottom hole located within NPS boundaries. To apply for an exemption, NPS requires the following information.

- Names and addresses of the operator; the mineral owner; and any

agents, assignees, designees, lessees, contractors, employees, or other representatives of the operator responsible for the overall management of the proposed operations.

- Documentation demonstrating the legal right to operate in an NPS unit.
- Contact information for the operator's representative responsible for field supervision of the proposed operations and for emergency response for the proposed operations.
- Maps and plats to scale showing the boundaries of each of the mineral tracts that are relevant to the proposed operations within the NPS unit boundary.
- Maps and plats to scale showing all proposed surface uses (well site, access route, flowlines, production facilities) that occur outside the NPS unit.
- Description, including depths, thicknesses, and properties of geologic horizons between the target zone and the base of the deepest aquifer.
- Drilling plan, including directional-drilling program, horizontal distance along the wellbore's path from well's surface location to the park boundary, depth at which wellbore crosses NPS unit boundary, and timeline for operations.
- Casing, cementing, and mud programs.
- Stimulation programs.
- Well plugging and abandonment program.
- If hydraulic fracturing is proposed, information required in § 9.89.

#### *Notification of Change*

Within 30 days, operators must notify NPS if the method of operation or environmental conditions of operation change.

#### **Operations Permit: Application Contents (§§ 9.80 Through 9.90)**

##### *All Applications*

All applications for an Operations Permit, must contain the following information:

- Documentation demonstrating the right to operate within an NPS unit.
- Contact information for the operator; the mineral owner; any agents, assignees, designees, contractors, or other representatives of the owner; and the operator's representative responsible for overall management, field supervision, and emergency response for the proposed operation.
- Existing condition and proposed area of operations, including all information required by § 9.84.
- Reclamation Plan, including (1) a description of the specific equipment and methods used to meet the operating

standards for reclamation (§ 9.116); and (2) a breakdown of the estimated costs that a third party would charge to complete reclamation as proposed in the reclamation plan.

- Use of water, including (1) the source, quantity, access route, and transportation/conveyance method for all water to be used in access road and pad construction, well drilling, stimulation, and production; and (2) estimations of any anticipated waste water volumes generated and how they will be managed (*i.e.*, handled, temporarily stored, disposed, recycled, reused) throughout stages of the operation.
- Environmental condition and mitigation actions, including all information required in § 9.85.
- Spill control and emergency preparedness plan, including all information required by § 9.86.

#### *Additional Information*

*Geophysical Exploration (§ 9.87).* If you are proposing geophysical exploration, the application must include:

- Number of crews and number of workers in each crew.
- Names and depths of geologic zones targeted for imaging.
- Description of the acquisition methods, including the procedures, specific equipment you will use, and energy sources (*e.g.*, explosives or vibroseis trucks).
- Methods of access along each survey line for personnel, materials, and equipment.
- List of all explosives, blasting equipment, chemicals, and fuels you will use in the proposed operations, including a description of proposed disposal methods, transportation methods, safety measures, and storage facilities.

• Map showing the positions of each survey line including all source and receiver locations as determined by a locational survey, and including shotpoint offset distances from wells, buildings, other infrastructure, and areas the NPS has indicated to you as environmentally sensitive areas.

*Drilling Operations (§ 9.88).* If you are proposing drilling operations, the application must include:

- Well-pad construction, including dimensions and cross sections of: Cut and fill areas and excavations for ditches, sumps, and spill control equipment or structures, including lined areas.
- Drill-rig and equipment layout, including rig components, fuel tanks, testing equipment, support facilities,

storage areas, and all other well-site equipment and facilities.

- Drilling program, including hole size for each section and the directional program, if applicable.
- Proposed drilling depth and the estimated depths and names of usable water, brine, hydrocarbon, geothermal, or other mineral-bearing zones.
- Type and characteristics of the proposed mud systems.
- Casing program, including the size, grade, weight, and setting depth of each string.
- Cementing program, including downhole location of any stage equipment, cement types, volumes, and additives to be used, and a description of pressure tests and cement verification techniques used that will be run to evaluate cement placement and integrity.
- Minimum specifications for pressure control equipment function and pressure testing frequency and the blowout preventer stack arrangement.
- Proposed logging, coring, and testing programs. Proposed completion program, including completion type (open-hole, perforated, slotted liner, etc.).
- Procedures, including considerations for well control.
- Description of the equipment, materials, and procedures proposed for well plugging, including plug depths, plug types, and minimum mud weight.

*Well Simulation Operations (§ 9.89).* If you are proposing well simulation operations, including hydraulic fracturing, the application must include:

- Geologic names, a geologic description, and the estimated depths (measured and true vertical) to the top and bottom of the formation into which hydraulic fracturing fluids are to be injected. The estimated minimum vertical distance between the top of the fracture zone and the nearest usable water zone, and the measured depth of the proposed perforated or open-hole interval.
- Estimated depths (measured and true vertical) to the top and bottom of the confining zone(s). Include a map showing the location, orientation, and extent of any known or suspected faults or fractures within one-half mile (horizontal distance) of the wellbore trajectory that may transect the confining zone(s).
- Map showing all existing wellbore trajectories, regardless of type, within one-half mile (horizontal distance) of any portion of the wellbore into which hydraulic fracturing fluids are to be injected. The true vertical depth of each wellbore identified on the map must be indicated.

- Steps to be taken before treatment to verify mechanical integrity of all downhole tubulars and tools and cement quality, including pressure tests and cement bond logs (or other logs acceptable to the Superintendent) demonstrating that the occurrences of usable water zones have been isolated to protect them from contamination.

- Detailed description of the proposed well-stimulation design, including:

- (1) Proposed stimulation fluid, including, but not limited to, the base fluid and each additive by trade name, and purpose of additive.

- (2) Proposed proppant system.

- (3) Estimated total volume of fluid to be used.

- (4) Anticipated surface treating pressure range.

- (5) Maximum anticipated surface pressure that will be applied during the hydraulic fracturing process.

- (6) Trajectory of the wellbore into which hydraulic fracturing fluids are to be injected and the estimated direction and length of the fractures that will be propagated and a notation indicating the true vertical depth of the top and bottom of the fractures; and

- (7) Any microseismic monitoring planned or proposed in conjunction with well stimulation.

- Source and location of water supply, such as reused or recycled water, rivers, creeks, springs, lakes, ponds, and water supply wells, and the source and location of water supply, such as reused or recycled water, rivers, creeks, springs, lakes, ponds, and water supply wells.

- Storage, mixing, pumping, and control equipment needed to perform the stimulation.

- Information on recovered fluids, including:

- (1) Estimated volume of stimulation fluids to be recovered during flow back.

- (2) Proposed methods of handling the recovered fluids including any onsite treatment for re-use of fluids in other stimulation activities.

- (3) Proposed disposal method of the recovered fluids, including, but not limited to, injection, hauling by truck, or transporting by pipeline.

*Production Operations (§ 9.90).* If you are proposing to produce a well, you must submit all of the following information:

- Dimensions and the to-scale layout of the wellpad, clearly identifying well locations, noting partial reclamation areas; gathering, separation, metering, and storage equipment; electrical lines; fences; spill control equipment or structures including lined areas, artificial lift equipment, tank batteries,

- treating and separating vessels, secondary or enhanced recovery facilities, water disposal facilities, gas compression and/or injection facilities; metering points; sales point (if on lease); tanker pick-up points; gas compressor, including size and type (if applicable); and any other well site equipment.

- Size, grade, weight, and setting depth of all casing and tubing strings; cementing history; type and size of packers and subsurface flow control devices; top and bottom depths of each completed interval; and method of completion.

- Well history, including completions, stimulations, servicing, and workovers.

- Minimum specifications for pressure-control equipment, function, and pressure-testing frequency.

- Method and means used to transport produced oil and gas, including vehicular transport; flowline and gathering line construction; operation; pipe size; operating pressure; cathodic protection methods; surface equipment use; surface equipment location; maintenance procedures; maintenance schedules; pressure detection methods; and shutdown procedures.

- Road and wellpad maintenance plan, including equipment and materials to maintain the road surface and control erosion.

- Vegetation management plan on well sites, roads, pipeline corridors, and other disturbed surface areas, including control of exotic species.

- Storm water management plan on the well site.

- Produced water storage and disposal plan.

- Procedures proposed for well plugging, the depths and the types of plugs, and minimum mud weight.

#### **Operating Standards (§§ 9.110–9.118)**

*Simulation operations (§ 9.118(a)).*

You must:

- Not begin injection activities before you demonstrate the mechanical integrity of all surface and downhole tubulars and equipment to differential pressures equal to at least those calculated at the maximum anticipated treating pressure. Continuously monitor and record the treating pressures and all annular pressures before, during, and after the treatment to ensure that treatment materials are directed to the intended zone.

- If mechanical integrity is lost during the treatment, immediately cease the operation and notify the Superintendent as soon as feasible, but no later than 24 hours after the incident.

- Within 15 days after the occurrence, submit to the Superintendent a report containing all details pertaining to the incident, including corrective actions taken.

*Production (§ 9.118(b)).* You must:

- Monitor producing conditions to document maintenance of mechanical integrity of both surface and subsurface equipment.

- Identify wells and related facilities by a sign, which must remain in place until the well is plugged and abandoned and the related facilities are closed. The sign must be of durable construction, and the lettering must be legible and large enough to be read under normal conditions at a distance of at least 50 feet. Each sign must show the name of the well, name of the operator, and the emergency contact phone number.

#### **General Terms and Conditions (§§ 9.120 Through 9.122)**

- Provide the NPS an affidavit, signed by an official who is authorized to legally bind the company, stating that proposed operations are in compliance with all applicable federal, state, and local laws and regulations and that all information submitted to the NPS is true and correct. (§ 9.120(c)).

- Third party monitor will report to NPS on compliance with permit. (§ 9.121(b)(2)).

- Notify the Superintendent of any accidents involving serious personal injury or death and of any fires or spills on the site within 24 hours after the accident occurs. (§ 9.121(c)).

- Submit a full written report on the accident to the Superintendent within 90 days after the accident occurs. (§ 9.121(c)).

- Notify the Superintendent within 24 hours after the discovery of any cultural or scientific resource you encounter that might be altered or destroyed by your operation. (§ 9.121(d)).

- Submit reports or other information necessary to verify compliance with your permit or with any provision of this subpart. (§ 9.121(d)).

- If your operations include hydraulic fracturing, you must provide the Superintendent with a report including all of the information below within 30 days after the completion of the last stage of hydraulic fracturing operations for each well (§ 9.122):

- (a) The true vertical depth of the well, total water volume used, and a description of the base fluid and each additive in the hydraulic fracturing fluid, including the trade name, supplier, purpose, ingredients, Chemical Abstract Service Number (CAS), maximum ingredient

concentration in additive (percent by mass), and maximum ingredient concentration in hydraulic fracturing fluid (percent by mass).

(b) The actual source(s) and location(s) of the water used in the hydraulic fracturing fluid;

(c) The maximum surface pressure and rate at the end of each stage of the hydraulic fracturing operation and the actual flush volume.

(d) The actual, estimated, or calculated fracture length, height, and direction.

(e) The actual measured depth of perforations or the open-hole interval.

(f) Actual volume of stimulation fluids recovered during flow back, including a description of how the volumes were measured or calculated.

(g) The following information concerning the handling of fluids recovered, covering the period between the commencement of hydraulic fracturing and the implementation of the approved permit for the disposal of produced water under NPS requirements:

(1) Methods of handling the recovered fluids, including, but not limited to, transfer pipes and tankers, holding pond use, re-use for other stimulation activities, or injection; and

(2) Disposal method of the recovered fluids, including, but not limited to, the percent injected, the percent stored at an off-lease disposal facility, and the percent recycled.

(h) Continuous monitoring records of annulus pressure at the bradenhead and other annular pressures that document pressures before, during, and after injection operations.

#### **Financial Assurance (§§ 9.140 Through 9.144)**

All operators are required to post adequate financial assurance with the NPS and are required to submit the following documentation to the NPS:

- Proof of financial assurance in a form acceptable to the Regional Director and payable upon demand.

- If necessary, an adjustment to the financial assurance amount because of any circumstance that increases or decreases the estimated costs.

#### **Modification to an Operation (§ 9.150)**

Operators may request or we may require an operator to modify their operations. To request a modification to an approved permit, operators must provide written notice to the Superintendent describing the modification and why it is needed.

#### **Change of Operator (§§ 9.160 and 9.161)**

If an operator transfers its operation to a new operator, both the old and new

operator must provide information to the NPS.

*Information Current Owner Must Provide.* When current operator transfers operations, current operator must:

- Notify the Superintendent in writing within 30 calendar days after the date the new owner acquires the rights to conduct operations providing:

(a) Names and addresses of the person or entity conveying the right and the person or entity acquiring the right.

(b) Effective date of transfer.

(c) Description of the rights, assets, and liabilities being transferred and which ones, if any, are being reserved by the previous owner.

(d) Written acknowledgement from the new owner that the contents of the notification are true and correct.

#### **Information New Operator Must Provide**

- Adopt and agree in writing to conduct operations in accordance with all terms and conditions of the previous operator's operations permit;

- File financial assurance with us that is acceptable to the Regional Director and made payable to the NPS.

If the previous operator was granted an exemption for accessing oil and gas rights from a surface location outside the park boundary, you must provide to the Superintendent:

- Documentation demonstrating that you hold the right to operate within an NPS unit;

- The names and addresses of the operator; the mineral owner; any agents, assignees, designees, lessees, or other representatives of the operator; the operator's representative responsible for the overall management of the proposed operations; the operator's representative responsible for field supervision of the proposed operations; and the operator's representative responsible for emergency response for the proposed operations.

#### **Well Plugging (§§ 9.170 and 9.171)**

An operator may apply for either an operations permit or a modification to its approved operations permit to maintain its well in a shut-in status for up to 5 years. The application must include the following information:

- Explanation of why the well is shut-in or temporarily abandoned and your future plans for utilization.

- Demonstration of the mechanical integrity of both surface and downhole equipment such that there is no migration of fluid from any formation in which it originally occurred or from the surface to the well.

- Description of the manner in which the operator well, equipment, and area of operations will be maintained.

#### **Reconsideration and Appeals (§§ 9.190 Through 9.194)**

To appeal an NPS decision, the operator must submit a written statement describing the alleged factual or legal errors in the original decision and requesting that the Regional Director reconsider the decision.

#### **Public Participation (§ 9.200)**

An operator may request that information required to be reported under these regulations concerning chemical formulations that are deemed to be trade secrets be withheld from disclosure. To make this request the operator must:

- Identify the owner of the withheld information and provide the name, address and contact information for a corporate officer, managing partner, or sole proprietor of the owner of the information.

- Identify the Federal statute or regulation that would prohibit the NPS from publicly disclosing the information if it were in the NPS's possession.

- Affirm that the operator has been provided the withheld information from the owner of the information and is maintaining records of the withheld information, or that the operator has access and will maintain access to the withheld information held by the owner of the information.

- Affirm that the information is not publicly available.

- Affirm that the information is not required to be publicly disclosed under any applicable laws and policies local, State, tribal, or Federal law;

- Affirm that the owner of the information is in actual competition and identifies competitors or others that could use the withheld information to cause the owner of the information substantial competitive harm;

- Affirm that the release of the information would likely cause substantial competitive harm to the owner of the information and provides the factual basis for that affirmation; and
- Affirm that the information is not readily apparent through reverse engineering with publicly available information.

*Title:* Non-Federal Oil and Gas Rights, 36 CFR part 9, subpart B.

*OMB Control Number:* 1024-XXXX.

*Service Form Number:* None.

*Type of Request:* Request for a new OMB control number.

*Description of Respondents:* Businesses.

*Respondent's Obligation:* Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Activity/requirement	Estimated number of annual responses	Completion time per response (hours)	Estimated total annual burden hours
Previously Exempt Operations (§§ 9.50–9.53) .....	106	10	1,060
Application for Temporary Access Permit (§§ 9.60–9.63) .....	5	15	75
Amendment of Temporary Access Permit .....	1	1	1
Accessing Oil and Gas Rights From a Surface Location Outside the Park Boundary—Application for Exemption (§§ 9.70–9.73) .....	3	80	240
Accessing Oil and Gas Rights From a Surface Location Outside the Park Boundary—Notice of change (§§ 9.70–9.73) .....	1	2	2
Operations Permit Operations Permit (New Operations):			
Application Contents—(§§ 9.80–9.90) .....	5	140	700
Operating Standards—Stimulation Operations (§ 9.118(b)):			
Demonstrate mechanical integrity .....	5	4	20
Record treating pressures and all annular pressures .....	5	4	20
Notify Superintendent if mechanical integrity is lost .....	1	1	1
Report of accident .....	2	1	2
Operating Standards—Production (§ 9.118(c)):			
Document maintenance of mechanical integrity .....	534	2	1,068
Signage to identify wells .....	5	4	20
General Terms and Conditions (§§ 9.120–9.122):			
Affidavit that proposed operations are in compliance with all laws and that information submitted to NPS is accurate .....	111	1	111
Third-Party Monitor Report .....	60	17	1,020
Notification—Accidents involving Serious Personal Injuries/Death and Fires/Spills .....	2	1	2
Written Report—Accidents Involving Serious Injuries/Deaths and Fires/Spills .....	2	16	32
Notification—Discovery of any cultural or scientific resources .....	1	1	1
Report—Verify Compliance with Permits .....	534	4	2,136
Reporting for Hydraulic Fracturing .....	1	2	2
Financial Assurance (§§ 9.140–9.144) .....	5	1	5
Modification to an Operation (§ 9.150) .....	1	16	16
Change of Operator (§§ 9.160–9.161) .....	5	8	40
Well Plugging (§§ 9.170–9.171) .....	33	14	462
Reconsideration and Appeals (§§ 9.190–9.194) .....	1	16	16
Public Participation (§ 9.200) .....	1	4	4
<b>Total</b> .....	<b>1,430</b>	<b>.....</b>	<b>7,056</b>

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on any aspect of this information collection, including:

- (1) Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this collection of information;
- (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.

Send your comments and suggestions on this information collection by the date indicated in the **DATES** section to the Desk Officer for the Department of the Interior at OMB–OIRA. See **ADDRESSES** section for instructions on submitting comments.

#### National Environmental Policy Act of 1969 (NEPA)

This rule constitutes a major Federal action with the potential to significantly affect the quality of the human environment. We have prepared the DEIS under the requirements of NEPA. The DEIS will publish shortly after this proposed rule and be available online at <http://parkplanning.nps.gov/DEIS9B>, by clicking on the link entitled “Document List.”

#### Effects on the Energy Supply (Executive Order 13211)

This proposed rule is not a significant energy action under the definition in Executive Order 13211. A statement of Energy Effects is not required.

#### Clarity of This Regulation

We are required by Executive Orders 12866 (section 1(b)(12)), 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you believe we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise this proposed rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you believe lists or tables would be useful, etc.

#### Drafting Information

This proposed rule reflects the collective efforts of NPS staff in the Geologic Resources Division, parks, and field offices, with assistance from the Division of Jurisdiction, Regulations and Special Park Uses.

## Public Participation

It is the policy of the Department of the Interior, whenever feasible, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments regarding this proposed rule by one of the methods listed in the **ADDRESSES** section. All comments must be received by midnight of the close of the comment period. Bulk comments in any format (hard copy or electronic) submitted on behalf of others will not be accepted.

We are particularly interested in comments concerning:

1. Substantive differences between NPS's proposed regulations of oil and gas activity and those of other Federal agencies, including differences in the associated costs and benefits.
2. The costs and benefits of not applying this rule to inholdings, and to operators' surface operations when accessing oil and gas rights inside an NPS unit from a surface location outside the park boundary.
3. Whether relevant guidance presently, or planned to be, included in the NPS 9B Operators Handbook should instead be included in this rule.
4. Whether the performance and operating standards are clear and certain in their purpose, including §§ 9.30(a), 9.103(a), 9.110(c), and 9.118.
5. Alternative approaches to removing public financial exposure including multi-well blanket bonding, the establishment of industry provided plugging fund, or increasing the financial assurance cap to a fixed amount higher than \$200,000. Please note that these alternatives were considered but dismissed from further analysis in the DEIS because they do not meet a fundamental purpose of the rulemaking, which is to ensure that bonding amounts are sufficient to meet reclamation needs and do not result in taxpayer liability.

## 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.

## List of Subjects

### 36 CFR Part 1

National parks, Penalties, Reporting and recordkeeping requirements

### 36 CFR Part 9

National parks, Oil and gas exploration, Reporting and recordkeeping requirements.

In consideration of the foregoing, the National Park Service proposes to amend 36 CFR parts 1 and 9 as follows:

## PART 1—GENERAL PROVISIONS

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

**Authority:** 54 U.S.C. 100101, 100751, 320102.

- 2. Revise § 1.3 to read as follows:

### § 1.3 Penalties.

(a) A person convicted of violating a provision of the regulations contained in parts 1 through 7, part 9 subpart B, and parts 12 and 13 of this chapter, within a park area not covered in paragraphs (b) or (c) of this section, shall be punished by a fine as provided by law, or by imprisonment not exceeding 6 months, or both, and shall be adjudged to pay all costs of the proceedings.

(b) A person who knowingly and willfully violates any provision of the regulations contained in parts 1 through 5, 7, part 9 subpart B, and part 12 of this chapter, within any national military park, battlefield site, national monument, or miscellaneous memorial transferred to the jurisdiction of the Secretary of the Interior from that of the Secretary of War by Executive Order No. 6166, June 10, 1933, and enumerated in Executive Order No. 6228, July 28, 1933, shall be punished by a fine as provided by law, or by imprisonment for not more than 3 months, or by both.

**Note:** These park areas are enumerated in a note under 5 U.S.C. 901.

(c) A person convicted of violating any provision of the regulations contained in parts 1 through 7, and part 9 subpart B of this chapter, within a park area established pursuant to the Act of August 21, 1935, 49 Stat. 666, shall be punished by a fine as provided by law and shall be adjudged to pay all costs of the proceedings. 54 U.S.C. 320105.

(d) Notwithstanding the provisions of paragraphs (a), (b) and (c) of this section, a person convicted of violating § 2.23 of this chapter shall be punished by a fine as provided by law. 16 U.S.C. 6811.

## PART 9—MINERALS MANAGEMENT

- 3. Revise subpart B to read as follows:

### Subpart B—Non-Federal Oil and Gas Rights

#### Purpose and Scope

Sec.

- 9.30 What is the purpose and scope of this subpart?
- 9.31 When does this subpart apply to me?
- 9.32 What authorization do I need to conduct operations?
- 9.33 If am already operating under an NPS authorization, what do I need to do?

#### Definitions

- 9.40 What do the terms used in this subpart mean?

#### Previously Exempt Operations

- 9.50 Do I need an operations permit for my previously exempt operations?
- 9.51 How do I apply for my operations permit?
- 9.52 What will the NPS do with my application?
- 9.53 May I continue to operate while the NPS reviews my application?

#### Temporary Access Permits

- 9.60 When do I need a temporary access permit?
- 9.61 How do I apply for a temporary access permit?
- 9.62 When will the NPS grant a temporary access permit?
- 9.63 How long will I have to conduct my reconnaissance surveys?

#### Accessing Oil and Gas Rights From a Surface Location Outside the Park Boundary

- 9.70 Do I need an operations permit for accessing oil and gas rights from outside the park boundary?
- 9.71 What information must I submit to the NPS?
- 9.72 How will the NPS act on my submission?
- 9.73 If I don't need an operations permit, are there still requirements that I must I meet?

#### Operations Permit: Application Contents

- 9.80 Who must apply for an operations permit?
- 9.81 May I use previously submitted information?
- 9.82 What must I include in my application?
- 9.83 What information must be included in all applications?
- 9.84 Existing conditions.
- 9.85 Environmental conditions and mitigation actions.
- 9.86 Spill control and emergency preparedness plan.
- 9.87 What additional information must be included if I am proposing geophysical exploration?
- 9.88 What additional information must be included if I am proposing drilling operations?
- 9.89 What additional information must be included if I am proposing well stimulation operations, including hydraulic fracturing?

9.90 What additional information must be included if I am proposing production operations?

#### Operations Permit: Application Review Process

- 9.100 How will NPS process my application?  
 9.101 How will the NPS conduct initial review?  
 9.102 How will the NPS conduct formal review?  
 9.103 What standards must be met to approve my application?  
 9.104 What final actions may the Regional Director take on my Operations Permit application?  
 9.105 What is the approval process for operations in Big Cypress National Preserve?

#### Operating Standards

- 9.110 What are the purposes and functions of NPS operating standards?  
 9.111 What general facility design and management standards must I meet?  
 9.112 What hydrologic standards must I meet?  
 9.113 What safety standards must I meet?  
 9.114 What lighting and visual standards must I meet?  
 9.115 What noise reduction standards must I meet?  
 9.116 What reclamation and protection standards must I meet?  
 9.117 What additional operating standards apply to geophysical operations?  
 9.118 What additional operating standards apply to drilling, stimulation, and production operations?

#### General Terms and Conditions

- 9.120 What terms and conditions apply to all operators?  
 9.121 What monitoring and reporting is required for all operators?  
 9.122 What additional reports must I submit if my operation includes hydraulic fracturing?

#### Access to Oil and Gas Rights

- 9.130 May I cross Federal property to reach the boundary of my mineral right?  
 9.131 Will the NPS charge me a fee for access?  
 9.132 Will I be charged a fee for emergency access to my operations?

#### Financial Assurance

- 9.140 Do I have to provide financial assurance to the NPS?  
 9.141 How does the NPS establish the amount of financial assurance?  
 9.142 Will the NPS adjust my financial assurance?  
 9.143 When will the NPS release my financial assurance?  
 9.144 Under what circumstances will I forfeit my financial assurance?

#### Modification to an Operation

- 9.150 Can my approved permit be modified?

#### Change of Operator

- 9.160 What are my responsibilities if I transfer my operations?

9.161 What must I do if operations are transferred to me?

#### Well Plugging

- 9.170 When must I plug my well?  
 9.171 Can I get an extension to the well plugging requirement?

#### Prohibitions and Penalties

- 9.180 What acts are prohibited under this subpart?  
 9.181 What enforcement actions can the NPS take?  
 9.182 How do violations affect my ability to obtain a permit?

#### Reconsideration and Appeals

- 9.190 Can I request reconsideration of NPS decisions?  
 9.191 How does the NPS process my request for reconsideration?  
 9.192 Can I appeal the Regional Director's decision?  
 9.193 Will filing a request for reconsideration or appeal stop the NPS from taking action under this subpart?  
 9.194 What if the original decision was made by the Superintendent?

#### Public Participation

- 9.200 How can the public participate in the approval process?

#### Information Collection

- 9.210 Has the Office of Management and Budget approved the information collection requirements?

#### Subpart B—Non-Federal Oil and Gas Rights

**Authority:** 16 U.S.C. 230a(a)(4), 459d-3, 460cc-2(i), 460ee(c)(4), 698c(b)(2), 698i(b)(2), and 698m-4; 18 U.S.C. 3571 and 3581; 31 U.S.C. 9701; 54 U.S.C. 100101, 100751, and 103104.

#### Purpose and Scope

##### § 9.30 What is the purpose and scope of this subpart?

(a) This subpart ensures that operators exercising non-federal oil and gas rights within an NPS unit use technologically feasible, least damaging methods to:

(1) Protect federally owned or administered lands, waters, or resources of NPS units;

(2) Protect NPS visitor uses or experiences, or visitor or employee health and safety; and

(3) Protect park resources and values under the statute commonly known as the NPS Organic Act;

(b) This subpart applies to all operators conducting non-federal oil or gas operations on lands or waters within an NPS unit, regardless of the ownership or jurisdictional status of those lands or waters.

(c) We do not intend for this subpart to result in a taking of a property interest. The purpose of this subpart is to reasonably regulate operations

affecting federally owned or administered lands, waters, and resources of NPS units, visitor uses and experiences, and visitor and employee health and safety.

##### § 9.31 When does this subpart apply to me?

(a) This subpart applies to you if you are an operator who conducts or proposes to conduct non-federal oil or gas operations.

(b) If you were operating outside of an NPS unit and your operation has been included within an existing NPS unit as a result of a change to the boundary, or included within a newly established NPS unit, you are subject to §§ 9.50 through 9.53.

(c) If you were operating under an exemption because your operation accessed oil and gas rights inside the park boundary from a surface location outside the park boundary, and your surface location has been included within an existing NPS unit as a result of a change to the boundary, or included within a newly established NPS unit, you are subject to §§ 9.50 through 9.53.

##### § 9.32 What authorization do I need to conduct operations?

(a) Except as provided in §§ 9.70 through 9.73, you must obtain a temporary access permit under §§ 9.60 through 9.63 or an operations permit under §§ 9.80 through 9.90 before starting operations.

(b) You must demonstrate that you have the right to operate in order to conduct activities within an NPS unit.

##### § 9.33 If I am already operating under an NPS authorization, what do I need to do?

(a) If you already have an NPS-approved plan of operations, you may continue to operate according to the terms and conditions of that approval, subject to the provisions of this subpart. For purposes of this subpart, we will consider your approved plan of operations to be either a temporary access permit or operations permit.

(b) This section applies to you if we have granted you an exemption to the plan of operations requirement because your operation accesses oil and gas rights inside a park boundary from a surface location outside the park's boundary. You may continue to operate under the exemption provided that your operations comply with the general terms and conditions of §§ 9.120 through 9.122. You are also subject to the prohibitions and penalties in §§ 9.180 through 9.182.



## Definitions

### § 9.40 What do the terms used in this subpart mean?

In addition to the definitions in 36 CFR 1.4, the following definitions apply to this subpart:

*Area of operations* means lands or waters within an NPS unit on which operations are approved to be carried out, including roads or other areas where you are authorized to exercise the oil and gas rights.

*Contaminating substance* means any toxic or hazardous substance which is used in or results from the conduct of operations and is listed under the Clean Water Act at 40 CFR part 116, the Resource Conservation and Recovery Act at 40 CFR part 261, or the Hazardous Materials Transportation Act at 49 CFR part 172. This includes, but is not limited to, explosives, radioactive materials, brine waters, formation waters, petroleum products, petroleum by-products, and chemical compounds used for drilling, production, processing, well testing, well completion, and well servicing.

*Gas* means any fluid, either combustible or noncombustible, which is produced in a natural state from the earth and which maintains a gaseous or rarefied state at ordinary temperature and pressure conditions.

*NPS unit* has the same meaning as "National Park System (Park Area)" defined at 36 CFR 1.4(a).

*Oil* means any viscous combustible liquid hydrocarbon or solid hydrocarbon substance easily liquefiable on warming that occurs naturally in the earth, including drip gasoline or other natural condensates recovered from gas without resort to manufacturing process.

*Operations* means all existing and proposed functions, work, and activities in connection with the exercise of oil or gas rights not owned by the United States and located or occurring within an NPS unit.

(1) Operations include, but are not limited to: Access by any means to or from an area of operations; construction; geological and geophysical exploration; drilling, well servicing, workover, or recompletion; production; gathering (including installation and maintenance of flowlines and gathering lines); storage, transport, or processing of petroleum products; earth moving; excavation; hauling; disposal; surveillance, inspection, monitoring, or maintenance of wells, facilities, and equipment; reclamation; road and pad building or improvement; shot hole and well plugging and abandonment, and

reclamation; and all other activities incident to any of the foregoing.

(2) Operations do not include reconnaissance surveys as defined in this subpart or oil and gas pipelines that are located within the park under authority of a deeded or other right-of-way.

*Operations permit* means an NPS special use permit authorizing an operator to conduct operations in an NPS unit. An operations permit is subject to cost recovery under 54 U.S.C. 103104.

*Operator* means any person or entity, agent, assignee, designee, lessee, or representative thereof who is conducting operations or proposing to exercise non-federal oil and gas rights within the boundaries of an NPS unit.

*Owner* means the person that holds title to non-federal oil and gas minerals.

*Previously exempt operations* means those operations being conducted in an NPS unit without an approved permit from the NPS as of the effective date of these regulations. This term does not include operations where, before the effective date of these regulations, the NPS granted the operator an exemption to the plan of operations requirement because the operation accessed oil and gas rights inside the park from a surface location outside the park.

*Reconnaissance survey* means an inspection or survey conducted by qualified specialists for the purpose of preparing a permit application.

(1) A reconnaissance survey includes identification of the area of operations and collection of natural and cultural resource information within and adjacent to the proposed area of operations.

(2) A reconnaissance survey does not include surface disturbance activities except for minimal disturbance necessary to perform cultural resource surveys, natural resource surveys, and location surveys required under this subpart.

*Right to operate* means a deed, lease, memorandum of lease, designation of operator, assignment of right, or other documentation demonstrating that you hold a legal right to conduct the operations you are proposing within an NPS unit.

*Technologically feasible, least damaging methods* are those that we determine, on a case-by-case basis, to be most protective of park resources and values while ensuring human health and safety, taking into consideration all relevant factors, including environmental, economic, and technological factors and the requirements of applicable law.

*Temporary access permit* means an NPS special use permit authorizing an operator to access that operator's proposed area of operations to conduct reconnaissance surveys necessary to collect basic information necessary to prepare an operations permit application. A temporary access permit is subject to cost recovery under 54 U.S.C. 103104.

*Third-party monitor* means a qualified specialist who is not an employee, agent, or representative of the operator and who has demonstrated to the NPS the relevant expertise to monitor operations for compliance with applicable laws, regulations, and permit requirements.

*Usable water* means an aquifer or its portion which supplies any public water system; or which contains a sufficient quantity of ground water to supply a public water system; and currently supplies drinking water for human consumption; or contains fewer than 10,000 mg/l total dissolved solids; and which is not an exempted aquifer.

*Waste* means any material that is discarded. It includes, but is not limited to: Drilling fluids and cuttings; produced fluids not under regulation as a toxic or hazardous substance; human waste; garbage; fuel drums; pipes; oil; contaminated soil; synthetic materials; man-made structures or equipment; or native and nonnative materials.

*We* and *us* mean the National Park Service.

*You* and *I* mean the operator, unless otherwise specified or indicated by the context.

## Previously Exempt Operations

### § 9.50 Do I need an operations permit for my previously exempt operations?

Yes. You must obtain an NPS operations permit in accordance with §§ 9.80 through 9.90.

### § 9.51 How do I apply for my operations permit?

Within 90 days after [effective date of the final rule] or within 90 days after the effective date of a boundary change, or establishment of a new NPS unit, as applicable, you must submit the following to the Superintendent of the NPS unit in which you propose to continue to conduct operations:

(a) A brief description of the current operations and any anticipated changes to the current operations;

(b) Documentation demonstrating that you hold the right to operate within an NPS unit;

(c) The State well-identification permit number or American Petroleum Institute (API) well number;

(d) Maps to scale that clearly delineate your proposed area of operations as of [effective date of the final rule] or the effective date of a boundary change, or establishment of a new NPS unit, as applicable, and that identify the area of surface disturbance and equipment layout within your proposed area of operations;

(e) A spill control environmental preparedness plan as required by § 9.86;

(f) Documentation of the current operating methods, surface equipment, downhole well construction and completion, materials produced or used, and monitoring methods;

(g) A description of how your proposed operation will meet each applicable operating standard in this subpart;

(h) A description of the procedures to be used and cost estimates for well plugging and surface reclamation; and

(i) The results of any reconnaissance surveys you have conducted to be used by the Superintendent to identify resource protection measures in your operations permit.

#### **§ 9.52 What will the NPS do with my application?**

The NPS will review your application and take action under §§ 9.100 through 9.104.

#### **§ 9.53 May I continue to operate while the NPS reviews my application?**

Before obtaining an approved operations permit, you may continue to conduct operations subject to the following conditions:

(a) Continuation of operations is limited to those methods and the area of disturbance that existed on [insert effective date] or the effective date of a boundary change, or establishment of a new NPS unit, as applicable.

(b) Your operation is also subject to the general terms and conditions in §§ 9.120 through 9.122 and the prohibitions and penalties in §§ 9.180 through 9.182.

(c) Except in an emergency, we will not take any steps to directly regulate your operation before 90 days after [effective date of the final rule] or 90 days after the effective date of a boundary change, or establishment of a new NPS unit, as applicable.

#### **Temporary Access Permits**

#### **§ 9.60 When do I need a temporary access permit?**

You must apply to the Regional Director for a temporary access permit to access your proposed area of operations in order to conduct reconnaissance surveys. This permit will describe the means, routes, timing,

and other terms and conditions of your access as determined by the Regional Director.

#### **§ 9.61 How do I apply for a temporary access permit?**

To apply for a temporary access permit, you must submit the following information to the Superintendent of the NPS unit in which you propose to conduct operations:

(a) A brief description of the intended future operation so that we can determine what information needs to be gathered;

(b) Documentation demonstrating that you hold a legal right to operate located within an NPS unit;

(c) The name, legal address, and telephone number of the owner, operator, employee, agent, or contractor responsible for overall management of the proposed operations;

(d) The name, legal address, telephone number, and qualifications of all specialists responsible for conducting the reconnaissance surveys;

(e) A map delineating the proposed reconnaissance survey area in relation to the park boundary and the proposed area of operations at a minimum scale of 1:24,000, or a scale specified by the Superintendent as acceptable;

(f) A description of proposed means of access and routes proposed for conducting the reconnaissance surveys; and

(g) A description of the survey methods you intend to use to identify the natural and cultural resources.

#### **§ 9.62 When will the NPS grant a temporary access permit?**

If the Regional Director determines that your proposed reconnaissance survey will not result in surface disturbance, except for minimal disturbance necessary to perform surveys, the Regional Director will issue you a temporary access permit within 30 days after receipt of a complete application, unless the Regional Director notifies you that additional time is necessary to evaluate or process your application.

#### **§ 9.63 How long will I have to conduct my reconnaissance surveys?**

Your temporary access permit will be in effect for a maximum of 60 days from the date of issuance. The Regional Director may extend the term of the temporary access permit for a reasonable period of time, based upon your written request that explains why an extension is necessary.

#### **Accessing Oil and Gas Rights From a Surface Location Outside the Park Boundary**

#### **§ 9.70 Do I need an operations permit for accessing oil and gas rights from outside the park boundary?**

Your downhole activities inside an NPS unit are subject to these regulations. If you wish to access your oil and gas rights located inside an NPS unit from a surface location outside the unit, you must submit the information required by § 9.71. We will evaluate this information to determine whether your operations are exempt or require an operations permit. We will require an operations permit only if we determine that permit requirements are needed to protect against a significant threat of damage to:

(a) Federally owned or administered lands, waters, or resources within NPS units;

(b) NPS visitor uses or experiences; or

(c) Visitor or employee health or safety.

#### **§ 9.71 What information must I submit to the NPS?**

You must provide the information required by this section to the Superintendent of the relevant NPS unit. You must provide all of the following.

(a) The names and addresses of:

(1) The operator;

(2) The mineral owner; and

(3) Any agents, assignees, designees, lessees, contractors, employees, or other representatives of the operator responsible for the overall management of the proposed operations.

(b) Documentation demonstrating that you hold a legal right to operate in an NPS unit.

(c) Contact information for the operator's representative responsible for field supervision of the proposed operations and for emergency response for the proposed operations.

(d) Maps and plats to scale showing the boundaries of each of the mineral tracts that are relevant to your proposed operations within the NPS unit boundary.

(e) Maps and plats to scale showing all proposed surface uses (well site, access route, flowlines, production facilities) that occur outside the NPS unit.

(f) Information regarding downhole operations and conditions, including:

(1) Description, including depths, thicknesses, and properties of geologic horizons between the target zone and the base of the deepest aquifer;

(2) Drilling plan, including directional-drilling program, horizontal

distance along the wellbore's path from well's surface location to the park boundary, depth at which wellbore crosses NPS unit boundary, and timeline for operations;

- (3) Casing, cementing, and mud programs;
- (4) Stimulation programs; and
- (5) Well plugging and abandonment program.
- (g) If you propose hydraulic fracturing, then you must also provide the information required by § 9.89.

**§ 9.72 How will the NPS act on my submission?**

- (a) Within 30 days after receiving your submission under § 9.71, the Superintendent will notify you in writing that your information is complete, you need to submit more information, or we need more time to review your submission.
- (b) Within 30 days after receiving your complete submission, the Superintendent will notify you in writing that either:
  - (1) No further action is required by the NPS and you are exempt from the operations permit requirement; or
  - (2) You must obtain an operations permit.
- (c) If you need an operations permit, the information provided under § 9.71 is your permit application and the NPS will review your application under §§ 9.100 through 9.104.

**§ 9.73 If I don't need an operations permit, are there still requirements that I must I meet?**

If the NPS notifies you under § 9.72 that you do not need an operations permit, you are still subject to the general terms and conditions in §§ 9.120 through 9.122, the prohibitions and penalties in §§ 9.180 through 9.182, and the requirements in this section.

- (a) You must notify the NPS within 30 days if your method of operation or the environmental conditions of your operation change.
- (b) The Regional Director may notify you in writing that you are no longer exempt from the operations permit requirement after determining that operational requirements are needed to protect against a significant threat of damage to any of the following:
  - (1) Federally owned or administered lands, waters, or resources of NPS units;
  - (2) NPS visitor uses or experiences; or
  - (3) Visitor or employee health or safety.
- (c) Within 30 days after receiving this notification, you must file your operations permit application with the Superintendent.

**Operations Permit: Application Contents**

**§ 9.80 Who must apply for an operations permit?**

Except as otherwise provided §§ 9.70 through 9.73, an operator proposing to conduct operations within the boundary of an NPS unit must submit an application for an operations permit to the Superintendent.

**§ 9.81 May I use previously submitted information?**

- (a) In satisfying the requirements of §§ 9.82 through 9.90, you do not need to resubmit information that is already on file with the NPS. Instead, you may reference the previously submitted information in your permit application.
- (b) You may submit documents and materials containing the information required by §§ 9.82 through 9.90 that you have submitted to other Federal and State agencies. If you do this, you must clearly identify the information required by §§ 9.82 through 9.90.

**§ 9.82 What must I include in my application?**

(a) Your application for an operations permit must include all of the information required by § 9.83. You must also submit the information required by §§ 9.87 through 9.90, where applicable, and any additional information that the Superintendent may require.

(b) You may provide information for only the phase of operations you propose. Each permit application is only required to describe those functions for which you want immediate approval. However, approval of an Operations Permit covering one phase of operations does not guarantee future approval of an Operations Permit covering a subsequent phase.

**§ 9.83 What information must be included in all applications?**

All applications must include the information required by this section.

All operations permit applications must include information on . . .	and must include the following detailed information . . .
(a) Ownership ..... (b) The owner/operator .....	documentation demonstrating that you hold the right to operate inside of an NPS unit. names, addresses, and other contact information for: (1) The operator; (2) The mineral owner; (3) Any agents, assignees, designees, contractors, or other representatives of the operator; (4) The operator's representatives responsible for overall management, field supervision, and emergency response for the proposed operations. all the information required by § 9.84.
(c) Existing conditions and proposed area of operations. (d) Reclamation plan .....	(1) A description of the specific equipment and methods used to meet the operating standards for reclamation at § 9.116; and (2) A breakdown of the estimated costs that a third party would charge to complete reclamation as proposed in your reclamation plan.
(e) Use of water .....	(1) The source, quantity, access route, and transportation/conveyance method for all water to be used in access road and pad construction, well drilling, stimulation, and production; and (2) Estimations of any anticipated waste water volumes generated and how they will be managed (i.e. handled, temporary stored, disposed, recycled, reused) throughout stages of the operation. all the information required by § 9.85.
(f) Environmental conditions and mitigation actions. (g) The spill control and emergency preparedness plan.	all the information required by § 9.86.

**§ 9.84 Existing conditions.**

(a) You must submit to-scale maps that clearly identify:

- (1) The boundaries of each of your mineral tracts in relation to your

proposed operations and the relevant NPS unit boundary;

(2) The natural features, including, but not limited to, streams, lakes, ponds, topographic relief, and areas the NPS has indicated to you as environmentally sensitive;

(3) The locations of existing roads, trails, railroad tracks, pads, and other disturbed areas; and

(4) The locations of existing structures that your operations could affect, including, but not limited to: Buildings, pipelines, producing oil and gas wells, freshwater wells, underground and overhead electrical lines, and other utility lines.

(b) You must submit the following information about geologic conditions under natural conditions and under the proposed operating conditions:

(1) Estimated depths and names of zones of usable water, brine, hydrocarbon, geothermal, or other mineral-bearing zones based on the best available information;

(2) Potential hazards to persons and the environment such as abnormal pressure zones, lost circulation zones, hydrogen sulfide gas, or karst formations; and

(3) Nature and extent (depth if known) of near-surface bedrock fracturing/jointing relative to proposed cemented surface casing-seat depth and any open annular interval proposed in the well design.

(c) You must submit the following information about new surface disturbances and construction:

(1) Maps showing the proposed area of operations; boundaries of new surface disturbances as determined by a location survey; and proposed access routes as determined by a location survey;

(2) Maps showing the proposed location of all support facilities, including those for transportation (*e.g.*, vehicle parking areas, airstrips, helicopter pads), sanitation, occupation, staging areas, fuel dumps, refueling areas, loading docks, water supplies, and disposal facilities;

(3) The method and diagrams, including cross-sections, of any proposed pad construction, road construction, cut-and-fill areas, and surface maintenance, including erosion control;

(4) The number and types of equipment and vehicles, including an estimate of vehicular round trips associated with each phase of your operation;

(5) An estimated timetable for each phase of the proposed operations, including any operational timing constraints;

(6) The type and extent of security measures proposed at your area of operations;

(7) The power sources and their transmission systems for the proposed operations; and

(8) The types and quantities of all solid and liquid waste generation and the proposed methods of storage, handling, and disposal.

#### **§ 9.85 Environmental conditions and mitigation actions.**

You must submit the following information about environmental conditions and mitigation actions:

(a) The natural resource and the cultural resource survey reports for your proposed area of operations;

(b) A description of the steps you propose to take to mitigate any adverse environmental impacts on park resources and values, including but not limited to, the unit's: Land features, land uses, fish and wildlife, vegetation, soils, surface and subsurface water resources, air quality, noise, lightscapes, viewsheds, cultural resources, and economic environment; and

(c) A discussion of:

(1) Any anticipated impacts that you cannot mitigate; and

(2) All alternative technologically feasible, least damaging methods of operations, their costs, and their environmental effects.

#### **§ 9.86 Spill control and emergency preparedness plan.**

You must submit the following information about your spill control and emergency preparedness plan. You may use a spill prevention control and countermeasure (SPCC) plan prepared under 40 CFR part 112 if the plan includes all of the information required by this section. You must submit:

(a) A list of names, addresses, and telephone numbers of persons that the Superintendent can contact in the event of a spill, fire, or accident, including the order in which the persons should be contacted;

(b) Notification and reporting procedure in the event of a spill, fire, or accident;

(c) Identification of contaminating or toxic substances used within your area of operations or expected to be encountered during operations;

(d) Identification of abnormal pressure, temperature, toxic gases or substances, or other hazardous conditions at your area of operations or expected to be encountered during operations;

(e) Measures (*e.g.*, procedures, facility design, equipment) to minimize risks to human health and safety and the environment;

(f) Steps to prevent accumulations of oil or other materials deemed to be fire hazards from occurring in the vicinity of well locations and lease tanks;

(g) The equipment and methods for containment and cleanup of contaminating substances, including a description of the equipment available at your area of operations and equipment available from local contractors;

(h) A storm water drainage plan and actions intended to mitigate storm water runoff;

(i) Safety data sheets for each material you will use or encounter during operations; including expected quantities maintained at your area of operations;

(j) A description of the emergency actions you will take in the event of accidents causing human injury; and

(k) Contingency plans for conditions and emergencies other than spills, such as if your area of operations is located in areas prone to hurricanes, flooding, tornadoes, fires, or earthquakes.

#### **§ 9.87 What additional information must be included if I am proposing geophysical exploration?**

If you propose to conduct geophysical exploration, you must submit the following additional information:

(a) The number of crews and numbers of workers in each crew;

(b) Names and depths of geologic zones targeted for imaging;

(c) A description of the acquisition methods, including the procedures, specific equipment you will use, and energy sources (*e.g.*, explosives or vibroseis trucks);

(d) The methods of access along each survey line for personnel, materials, and equipment;

(e) A list of all explosives, blasting equipment, chemicals, and fuels you will use in the proposed operations, including a description of proposed disposal methods, transportation methods, safety measures, and storage facilities; and

(f) A map showing the positions of each survey line including all source and receiver locations as determined by a locational survey, and including shotpoint offset distances from wells, buildings, other infrastructure, and areas the NPS has indicated to you as environmentally sensitive areas.

#### **§ 9.88 What additional information must be included if I am proposing drilling operations?**

If you are proposing to drill a well, you must submit the following additional information:

(a) Well-pad construction, including dimensions and cross sections of: Cut

and fill areas and excavations for ditches, sumps, and spill control equipment or structures, including lined areas;

(b) Drill-rig and equipment layout, including rig components, fuel tanks, testing equipment, support facilities, storage areas, and all other well-site equipment and facilities;

(c) The drilling program, including hole size for each section and the directional program, if applicable;

(d) Proposed drilling depth and the estimated depths and names of usable water, brine, hydrocarbon, geothermal, or other mineral-bearing zones;

(e) The type and characteristics of the proposed mud systems;

(f) The casing program, including the size, grade, weight, and setting depth of each string;

(g) The cementing program, including downhole location of any stage equipment, cement types, volumes, and additives to be used, and a description of pressure tests and cement verification techniques used that will be run to evaluate cement placement and integrity;

(h) The minimum specifications for pressure control equipment function and pressure testing frequency and the blowout preventer stack arrangement;

(i) The proposed logging, coring, and testing programs;

(j) The proposed completion program, including completion type (open-hole, perforated, slotted liner, etc.) and procedures, including considerations for well control; and

(k) A description of the equipment, materials, and procedures proposed for well plugging, including plug depths, plug types, and minimum mud weight.

**§ 9.89 What additional information must be included if I am proposing well-stimulation operations, including hydraulic fracturing?**

If you are proposing well stimulation operations, including hydraulic fracturing, you must submit the following additional information:

(a) The geologic names, a geologic description, and the estimated depths (measured and true vertical) to the top and bottom of the formation into which hydraulic fracturing fluids are to be injected. The estimated minimum vertical distance between the top of the fracture zone and the nearest usable water zone, and the measured depth of the proposed perforated or open-hole interval.

(b) The estimated depths (measured and true vertical) to the top and bottom of the confining zone(s). Include a map showing the location, orientation, and extent of any known or suspected faults or fractures within one-half mile

(horizontal distance) of the wellbore trajectory that may transect the confining zone(s).

(c) A map showing all existing wellbore trajectories, regardless of type, within one-half mile (horizontal distance) of any portion of the wellbore into which hydraulic fracturing fluids are to be injected. The true vertical depth of each wellbore identified on the map must be indicated.

(d) Steps to be taken before treatment to verify mechanical integrity of all downhole tubulars and tools and cement quality, including pressure tests, monitoring of cement returns to surface, and cement evaluation logs (or other logs acceptable to the Superintendent) demonstrating that the occurrences of usable water zones have been isolated to protect them from contamination.

(e) A detailed description of the proposed well-stimulation design, including:

(1) The proposed stimulation fluid, including, but not limited to, the base fluid and each additive by trade name, and purpose of additive;

(2) Proposed proppant system;

(3) The estimated total volume of fluid to be used;

(4) The anticipated surface treating pressure range;

(5) The maximum anticipated surface pressure that will be applied during the hydraulic fracturing process;

(6) The trajectory of the wellbore into which hydraulic fracturing fluids are to be injected and the estimated direction and length of the fractures that will be propagated and a notation indicating the true vertical depth of the top and bottom of the fractures; and

(7) Any microseismic monitoring planned or proposed in conjunction with well stimulation.

(f) The source and location of water supply, such as reused or recycled water, rivers, creeks, springs, lakes, ponds, and water supply wells, and the source and location of water supply, such as reused or recycled water, rivers, creeks, springs, lakes, ponds, and water supply wells.

(g) The storage, mixing, pumping, and control equipment needed to perform the stimulation.

(h) The following information concerning the handling of recovered fluids:

(1) The estimated volume of stimulation fluids to be recovered during flow back;

(2) The proposed methods of handling the recovered fluids including any onsite treatment for re-use of fluids in other stimulation activities; and

(3) The proposed disposal method of the recovered fluids, including, but not

limited to, injection, hauling by truck, or transporting by pipeline.

**§ 9.90 What additional information must be included if I am proposing production operations?**

If you are proposing to produce a well, you must submit all of the following information:

(a) The dimensions and the to-scale layout of the wellpad, clearly identifying well locations, noting partial reclamation areas; gathering, separation, metering, and storage equipment; electrical lines; fences; spill control equipment or structures including lined areas, artificial lift equipment, tank batteries, treating and separating vessels, secondary or enhanced recovery facilities, water disposal facilities, gas compression and/or injection facilities; metering points; sales point (if on lease); tanker pick-up points; gas compressor, including size and type (if applicable); and any other well site equipment;

(b) The size, grade, weight, and setting depth of all casing and tubing strings; cementing history; type and size of packers and subsurface flow control devices; top and bottom depths of each completed interval; and method of completion;

(c) The well history, including completions, stimulations, servicing, and workovers;

(d) The minimum specifications for pressure-control equipment, function, and pressure-testing frequency;

(e) The method and means used to transport produced oil and gas, including vehicular transport; flowline and gathering line construction; operation; pipe size; operating pressure; cathodic protection methods; surface equipment use; surface equipment location; maintenance procedures; maintenance schedules; pressure detection methods; and shutdown procedures;

(f) Road and wellpad maintenance plan, including equipment and materials to maintain the road surface and control erosion;

(g) Vegetation management plan on well sites, roads, pipeline corridors, and other disturbed surface areas, including control of exotic species;

(h) Storm water management plan on the well site;

(i) Produced water storage and disposal plan; and

(j) The procedures proposed for well plugging, the depths and the types of plugs, and minimum mud weight.

**Operations Permit: Application Review Process****§ 9.100 How will NPS process my application?**

We will conduct initial review of your application to determine if all information is complete. Once your information is complete, we can begin formal review. If you propose operations in Big Cypress National Preserve, the requirements in § 9.105 apply instead of those in § 9.101 and § 9.102.

**§ 9.101 How will the NPS conduct initial review?**

(a) Within 30 days after receipt of your application, the Superintendent will notify you in writing that either:

(1) Your application is complete and the NPS will begin formal review;

(2) Your permit application does not meet the information requirements and additional information is required before the NPS will conduct formal review of your permit application; or

(3) More time is necessary to complete the review, in which case the NPS will provide you an estimate of the amount of additional time reasonably needed and an explanation for the delay.

(b) If you resubmit information requested by the NPS under this section and the Superintendent determines that you have met all applicable information requirements, the Superintendent will notify you within 30 days after receipt of the additional information that either:

(1) Your application is complete and the NPS will begin formal review; or

(2) More time is necessary to complete the review, in which case the NPS will provide you an estimate of the amount of additional time reasonably needed and an explanation for the delay.

**§ 9.102 How will the NPS conduct formal review?**

(a) The Superintendent will evaluate the potential impacts of your proposal on federally owned or administered lands, waters, or resources within NPS units, visitor uses and experiences, and visitor and employee health and safety. As part of this evaluation process, the NPS will comply with all applicable federal laws, including the National Environmental Policy Act of 1969. The Superintendent will then make a recommendation to the Regional Director regarding final action on your operations permit.

(b) As part of the evaluation process, the Superintendent may consult with other Federal, State, and local agencies.

**§ 9.103 What standards must be met to approve my application?**

(a) In order to approve your operations permit application, the

Regional Director first must determine that your operations:

(1) Will not impair park resources and values under the statute commonly known as the NPS Organic Act;

(2) Will meet all applicable operating standards; and

(3) Will comply with all applicable Federal, State, and local laws and regulations.

(b) Before approval of your permit application, you must submit to the Superintendent:

(1) Financial assurance in the amount specified by the Regional Director and in accordance with the requirements of §§ 9.140 through 9.144; and

(2) Proof of liability insurance with limits sufficient to cover injuries to persons or property caused by your operations.

**§ 9.104 What final actions may the Regional Director take on my Operations Permit application?**

(a) The Regional Director will take final action within 180 days after the date the NPS deems your application complete unless:

(1) We and you agree that such final action will occur within a shorter or longer period of time; or

(2) We determine that an additional period of time is required to ensure that we have, in reviewing the permit application, complied with other applicable laws, Executive orders, and regulations.

(b) The Regional Director will notify you in writing that your permit application is:

(1) Approved, and provide you a list of required operating conditions; or

(2) Denied, and provide you justification for the denial. Any such denial must be consistent with § 9.30(c).

**§ 9.105 What is the approval process for operations in Big Cypress National Preserve?**

(a) Within 30 days after the date of submission of your application, we will notify you whether the application contains all information reasonably necessary to allow us to consider the application and, if not, will request that you provide additional information. After receiving this notification, you must either supply any reasonably necessary additional information or must notify us that you believe that the application contains all reasonably necessary information and is therefore complete; whereupon we may:

(1) Within 30 days after receipt of the notice from the applicant, determine that the application does not contain all reasonably necessary additional information and, on that basis, deny the application; or

(2) Review the application and take final action within 60 days after the date that you provided notification to the NPS that your application is complete.

(b) The Regional Director will take final action within 90 days after the date you submitted your application unless:

(1) We and you agree that final action can occur within a shorter or longer period of time; or

(2) We determine that an additional period of time is required to ensure that we have, in reviewing the permit application, complied with other applicable laws, executive orders, and regulations.

**Operating Standards****§ 9.110 What are the purposes and functions of NPS operating standards?**

(a) You must comply with all operating standards in §§ 9.111 through 9.116, as well as with the standards in §§ 9.117 and 9.118, if applicable. The standards apply only to operations that occur within a park unit, including downhole activities, and do not apply to surface activities located outside a park unit. These operating standards are incorporated into the terms and conditions of your operations permit. Violation of these operating standards will subject you to the prohibitions and penalties provisions of §§ 9.180 through 9.182.

(b) NPS operating standards ensure protection of federally owned administered lands, waters, and resources of NPS units, visitor uses and experiences, and visitor and employee health and safety. The operating standards give us and the operator flexibility to consider using alternative methods, equipment, materials design, and conduct of operations.

(c) In applying standards to a particular operation, you must use technologically feasible, least damaging methods to protect federally owned or administered lands, waters, and resources of NPS units, visitor uses and experiences, and visitor and employee health and safety.

**§ 9.111 What general facility design and management standards must I meet?**

(a) You must design, construct, operate, and maintain access to your operational site to cause the minimum amount of surface disturbance needed to safely conduct operations and to avoid areas the NPS has indicated to you as sensitive resources.

(b) You must install and maintain secondary containment materials and structures for all equipment and facilities using or storing contaminating substances. The containment system must be sufficiently impervious to

prevent discharge and must have sufficient storage capacity to contain, at a minimum, the largest potential spill incident.

(c) You must keep temporarily stored waste in the smallest feasible area, and confine it to prevent escape as a result of percolation, rain, high water, or other causes. You must regularly remove waste from the NPS unit and lawfully dispose of it in a direct and workable timeframe. Under 36 CFR part 6, you may not establish a solid waste disposal site in an NPS unit.

(d) You must use engines that adhere to current Federal and State emission standards.

(e) You must construct, maintain, and use roads to minimize fugitive dust emissions;

(f) You must use equipment and practices that minimize releases or flaring of gas.

(g) You must provide a safe environment for fish and wildlife free from exposure to physical and chemical hazards.

(h) You must control the invasion of exotic plant and animal species in your area of operations from the beginning through final reclamation.

#### **§ 9.112 What hydrologic standards must I meet?**

(a) You must not conduct ground-disturbing operations within 500 feet of surface water, including an intermittent or ephemeral watercourse, or wetland; or within 500 feet of any structure or facility used by the NPS for interpretation, public recreation, or administration. The Superintendent may increase or decrease this distance as needed to protect federally owned or administered lands, waters, or resources of NPS units, visitor uses or experiences, or visitor or employee health and safety. Measurements for purposes of this paragraph are by map distance.

(b) You must construct facilities in a manner that maintains hydrologic connectivity between surface water and groundwater.

(c) You must not cause measureable degradation of surface water or groundwater beyond that of existing conditions.

(d) You must conduct operations in a manner that maintains natural processes of erosion and sedimentation.

#### **§ 9.113 What safety standards must I meet?**

(a) You must maintain your area of operations in a manner that avoids or minimizes the cause or spread of fires and does not intensify fires originating outside your operations area.

(b) You must maintain structures, facilities, improvements, and equipment in a safe and professional manner in order to provide a safe environment for park resources, park visitors, and NPS employees, free from exposure to physical and chemical hazards.

(c) You must provide site-security measures to protect visitors from hazardous conditions resulting from the conduct of your operations.

#### **§ 9.114 What lighting and visual standards must I meet?**

(a) You must design, shield, and focus lighting to minimize the effects of spill light on the night sky or adjacent areas.

(b) You must reduce visual contrast in the landscape by selecting the area of operations, avoiding unnecessary disturbance, choosing appropriate colors for permanent facilities, and other means.

(c) You must use road and pad materials similar in structure to soils in surrounding profiles whenever feasible.

#### **§ 9.115 What noise reduction standards must I meet?**

You must prevent or minimize all noise that:

(a) Adversely affects the natural soundscape or other park resources or values, taking into account frequency, magnitude, or duration; or

(b) Exceeds levels that have been identified through monitoring as being acceptable to or appropriate for visitor uses at the sites being monitored.

#### **§ 9.116 What reclamation and protection standards must I meet?**

(a) You must promptly clean up and remove any released contaminating substances and provide documentation to the Superintendent that the substances were disposed of in accordance with all applicable Federal, State, and local laws.

(b) You must perform partial reclamation of areas no longer necessary to conduct operations. You must begin final reclamation as soon as possible but no later than 6 months after you complete your permitted operations unless the Regional Director authorizes a longer period in writing.

(c) You must protect all survey monuments, witness corners, reference monuments, and bearing trees against destruction, obliteration, or damage from operations. You are responsible for reestablishment, restoration, and referencing of any monuments, corners and bearing trees that are destroyed, obliterated, or damaged by your operations.

(d) You must complete reclamation by:

(1) Plugging all wells;

(2) Removing all above-ground structures, equipment, and roads and all other man-made material and debris resulting from operations;

(3) Removing or neutralizing any contaminating substances;

(4) Reestablishing native vegetative communities, or providing for conditions where ecological processes typical of the ecological zone (e.g., plant or wildlife succession) will reestablish themselves;

(5) Grading to reasonably conform the contours to preexisting elevations that are most appropriate to maximizing ecologic functional value;

(6) Restoring conditions to pre-disturbance hydrologic movement and functionality;

(7) Restoring natural systems using native soil material that is similar in character to the adjacent undisturbed soil profiles;

(8) Ensuring that reclaimed areas do not interfere with visitor use or with administration of the unit;

(9) Meeting conditions compatible with the management objectives of the park; and

(10) Ensuring proper and equitable apportionment of reclamation responsibilities by coordinating with us or with other operators who may be using a portion of your area of operations.

#### **§ 9.117 What additional operating standards apply to geophysical operations?**

If you conduct geophysical operations, you must do all of the following:

(a) Use surveying methods that minimize the need for vegetative trimming and removal;

(b) Locate source points using industry-accepted minimum safe-offset distances from pipelines, telephone lines, railroad tracks, roads, power lines, water wells, oil and gas wells, oil and gas-production facilities, and buildings;

(c) Use equipment and methods that, based upon the specific environment, will minimize impacts to federally owned or administered lands, waters, and resources of NPS units, visitor uses and experiences, and visitor and employee health and safety; and

(d) If you use shot holes, you must:

(1) Use biodegradable charges;

(2) Plug all shot holes to prevent a pathway for migration for fluids along any portion of the bore; and

(3) Leave the site in a clean and safe condition that will not impede surface reclamation or pose a hazard to human health and safety.

**§ 9.118 What additional operating standards apply to drilling, stimulation, and production operations?**

If you conduct drilling, stimulation, and production operations, you must meet all of the standards in this section.

(a) *Drilling.* (1) You must use containerized mud circulation systems for operations.

(2) You must not create earthen pits for any use. Earthen pits used solely for secondary containment on sites existing before [effective date of the final rule] may continue in use; however, the Superintendent may require such structures to be lined or removed depending on site-specific operational and environmental conditions.

(3) You must take all necessary precautions to keep your wells under control at all times, use only contractors or employees trained and competent to drill and operate the wells, and use only oil field equipment and practices generally used in the industry.

(4) You must design, implement, and maintain integrated casing, cementing, drilling fluid, completion, stimulation, and blowout prevention programs. These programs must be based upon sound engineering principles to prevent escape of fluids to the surface and to isolate and protect usable water zones throughout the life of the well, taking into account all relevant geologic and engineering factors.

(b) *Stimulation operations including hydraulic fracturing.* (1) You must not begin injection activities before you demonstrate the mechanical integrity of all surface and downhole tubulars and equipment to differential pressures equal to at least those calculated at the maximum anticipated treating pressure.

(2) You must continuously monitor and record the treating pressures and all annular pressures before, during, and after the treatment to ensure that treatment materials are directed to the intended zone.

(3) If mechanical integrity is lost during the treatment, you must immediately cease the operation and notify the Superintendent as soon as feasible, but no later than 24 hours after the incident. Within 15 days after the occurrence, you must submit to the Superintendent a report containing all details pertaining to the incident, including corrective actions taken.

(c) *Production.* (1) You must monitor producing conditions to document maintenance of mechanical integrity of both surface and subsurface equipment.

(2) You must maintain your well to prevent escape of fluids to the surface and to isolate and protect usable water zones throughout the life of the well,

taking into account all relevant geologic and engineering factors.

(3) You must identify wells and related facilities by a sign, which must remain in place until the well is plugged and abandoned and the related facilities are closed. The sign must be of durable construction, and the lettering must be legible and large enough to be read under normal conditions at a distance of at least 50 feet. Each sign must show the name of the well, name of the operator, and the emergency contact phone number.

(4) You must remove all equipment and materials that are no longer needed for a particular phase of your operation.

(5) You must plug all wells to:

(i) Prevent a pathway of migration for fluids along any portion of the bore; and

(ii) Leave the surface in a clean and safe condition that will not impede surface reclamation or pose a hazard to human health and safety.

**General Terms and Conditions**

**§ 9.120 What terms and conditions apply to all operators?**

The following terms and conditions apply to all operators, regardless of whether these terms and conditions are expressly included in the operator's operations permit:

(a) The operator/permittee is responsible for ensuring that all of its contractors and subcontractors comply fully with all of the requirements of this subpart;

(b) The operator/permittee may not use any surface water or groundwater owned or administered by the United States that has been diverted or withdrawn from a source located within the boundaries of an NPS unit unless the use has been approved in accordance with NPS policy;

(c) The operator/permittee must provide the NPS an affidavit, signed by an official who is authorized to legally bind the company, stating that proposed operations are in compliance with all applicable federal, state, and local laws and regulations and that all information submitted to the NPS is true and correct; and

(d) The operator/permittee agrees to indemnify and hold harmless the United States and its officers and employees from and against any and all liability of any kind whatsoever arising out of or resulting from the acts or omissions of the operator and its employees, agents, representatives, contractors, and subcontractors in the conduct of activities under the operations permit.

**§ 9.121 What monitoring and reporting is required for all operators?**

(a) The NPS may access your area of operations at any time to monitor the potential effects of the operations and to ensure compliance with this subpart where applicable.

(b) The Regional Director may determine that third-party monitors are necessary to protect federally owned or administered lands, waters, or resources of NPS units, visitor uses or experiences, or visitor or employee health and safety.

(1) The Regional Director's determination will be based on the scope and complexity of the proposed operation and whether the park has the staff and technical ability to ensure compliance with the operations permit and any provision of this subpart.

(2) A third-party monitor will report directly to the NPS at intervals determined by the Superintendent, and you will be responsible for the cost of the third party monitor. We will make the information reported available to you upon your request.

(c) You must notify the Superintendent of any accidents involving serious personal injury or death and of any fires or spills on the site within 24 hours after the accident occurs. You must submit a full written report on the accident to the Superintendent within 90 days after the accident occurs.

(d) You must notify the Superintendent within 24 hours after the discovery of any cultural or scientific resource you encounter that might be altered or destroyed by your operation. You must cease operations if necessary and leave the discovered resource intact until the Superintendent provides you with instructions. The Superintendent will determine, within 10 working days after notification what action will be taken with respect to the discovery.

(e) Upon the Superintendent's request, you must submit reports or other information necessary to verify compliance with your permit or with any provision of this subpart. To fulfill this request, you may submit to the NPS reports that you have submitted to the State under State regulations, or that you have submitted to any other Federal agency.

**§ 9.122 What additional reports must I submit if my operation includes hydraulic fracturing?**

If your operations include hydraulic fracturing, you must provide the Superintendent with a report including all of the following details of the stimulation within 30 days after the



completion of the last stage of hydraulic fracturing operations for each well. The information required in paragraph (a) of this section must be submitted to the authorized officer through FracFocus or another NPS-designated database:

(a) The true vertical depth of the well, total water volume used, and a description of the base fluid and each additive in the hydraulic fracturing fluid, including the trade name, supplier, purpose, ingredients, Chemical Abstract Service Number (CAS), maximum ingredient concentration in additive (percent by mass), and maximum ingredient concentration in hydraulic fracturing fluid (percent by mass).

(b) The actual source(s) and location(s) of the water used in the hydraulic fracturing fluid;

(c) The maximum surface pressure and rate at the end of each stage of the hydraulic fracturing operation and the actual flush volume.

(d) The actual, estimated, or calculated fracture length, height and direction.

(e) The actual measured depth of perforations or the open-hole interval.

(f) You must submit the actual volume of stimulation fluids recovered during flow back, including a description of how the volumes were measured or calculated.

(g) The following information concerning the handling of fluids recovered, covering the period between the commencement of hydraulic fracturing and the implementation of the approved permit for the disposal of produced water under NPS requirements:

(1) The methods of handling the recovered fluids, including, but not limited to, transfer pipes and tankers, holding pond use, re-use for other stimulation activities, or injection; and

(2) The disposal method of the recovered fluids, including, but not limited to, the percent injected, the percent stored at an off-lease disposal facility, and the percent recycled.

(h) You must submit continuous monitoring records of annulus pressure at the bradenhead and other annular pressures that document pressures before, during, and after injection operations. You must submit a signed certification that wellbore integrity was maintained throughout the operation.

#### Access to Oil and Gas Rights

##### **§ 9.130 May I cross Federal property to reach the boundary of my oil and gas right?**

(a) The Regional Director may grant you the privilege of access on, across, or through federally owned or

administered lands or waters in any NPS unit to reach the boundary of your oil and gas right.

(b) In NPS units in Alaska, regulations and standards at 43 CFR part 36 govern access to an operator's oil and gas right.

##### **§ 9.131 Will the NPS charge me a fee for access?**

(a) The Regional Director may charge you a fee if you use federally owned or administered lands or waters outside the scope of your oil and gas right.

(1) If you require use of federally owned or administered lands or waters for your operation, the Regional Director will charge you a fee based on the fair market value of the use of the lands for access.

(2) If access to your mineral right is across an existing park road, the Regional Director will charge the fee according to a posted fee schedule.

(b) Fees under this section will not be charged for access within the scope of your oil and gas right or access to your mineral right that is otherwise provided for by law.

##### **§ 9.132 Will I be charged a fee for emergency access to my operations?**

The Regional Director will not charge a fee for access across federally owned or administered lands beyond the scope of your oil and gas right as necessary to respond to an emergency situation at your area of operations if the Regional Director determines that the circumstances require an immediate response to either:

(a) Prevent or to minimize injury to park resources; or

(b) Ensure public health and safety.

#### Financial Assurance

##### **§ 9.140 Do I have to provide financial assurance to the NPS?**

Yes. You must file financial assurance with us in a form acceptable to the Regional Director and payable upon demand. This financial assurance is in addition to any financial assurance required by any other regulatory authority.

##### **§ 9.141 How does the NPS establish the amount of financial assurance?**

We will base the financial assurance amount upon the estimated cost for a third-party contractor to complete reclamation in accordance with this subpart. If the cost of reclamation exceeds the amount of your financial assurance, you will remain liable for all costs of reclamation in excess of the financial assurance.

##### **§ 9.142 Will the NPS adjust my financial assurance?**

The Regional Director may require, or you may request, an adjustment to the financial assurance amount because of any circumstance that increases or decreases the estimated costs established under § 9.141.

##### **§ 9.143 When will the NPS release my financial assurance?**

(a) Your responsibility and that of any surety under the financial assurance will continue until either:

(1) The Regional Director determines that you have met all applicable reclamation operating standards and any additional reclamation requirements that may be included in your operations permit; or

(2) A new operator assumes your operations, as provided in §§ 9.160 through 9.161.

(b) You will be notified within 30 days after the Regional Director's determination that your financial assurance has been released.

##### **§ 9.144 Under what circumstances will I forfeit my financial assurance?**

(a) You will forfeit all or part of your financial assurance if all efforts to secure your compliance with your reclamation responsibilities under the approved permit or any provisions of this regulation are unsuccessful.

(b) If you forfeit your financial assurance, we may:

(1) Prohibit you from removing all structures, equipment, or other materials from your area of operations;

(2) Require you to secure the operations site and take any necessary actions to protect federally owned or administered lands, waters, or resources of NPS units, visitor uses or experiences, or visitor or employee health and safety; and

(3) Suspend review of any permit applications you have submitted until the Regional Director determines that all violations of permit provisions or of any provision of this subpart are resolved.

(4) Seek recovery as provided in § 9.141 for all costs of reclamation in excess of the posted financial assurance.

#### Modification to an Operation

##### **§ 9.150 Can my approved permit be modified?**

The Regional Director may modify an approved temporary access or operations permit to adjust to changed conditions or to address unanticipated conditions, either unilaterally or at your request.

(a) To request a modification to your approved permit, you must provide written notice to the Superintendent

describing the modification and why it is needed. The Regional Director will review your request for modification, under the approval standards and timeframes at § 9.62 or 9.104.

(b) If the Regional Director authorizes a modification to your permit, you will receive a written notice that:

(1) Describes the modification required and justification; and  
(2) Specifies the time within which you must incorporate the modification into your operations.

(c) You may not implement any modification until you have received the Regional Director's written approval.

### Change of Operator

#### § 9.160 What are my responsibilities if I transfer my operations?

Until you meet the requirements of this subpart and the Regional Director accepts the new operator's financial assurance, you remain responsible for compliance with your operations permit and we will retain your financial assurance.

(a) If you were operating without an operations permit, you are subject to §§ 9.120 through 9.122 and §§ 9.180 through 9.182 until the new operator meets the requirements of this subpart and the Regional Director accepts the new operator's financial assurance.

(b) You must notify the Superintendent in writing within 30 calendar days after the date the new owner acquires the rights to conduct operations. Your written notification must include:

- (1) The names and addresses of the person or entity conveying the right and the person or entity acquiring the right;
- (2) The effective date of transfer;
- (3) The description of the rights, assets, and liabilities being transferred and which ones, if any, are being reserved by the previous owner, and
- (4) A written acknowledgement from the new owner that the contents of the notification are true and correct.

#### § 9.161 What must I do if operations are transferred to me?

(a) If another operator transfers operations to you, you must:

(1) Adopt and agree in writing to conduct operations in accordance with all terms and conditions of the previous operator's operations permit; and

(2) File financial assurance with us that is acceptable to the Regional Director and made payable to the NPS.

(b) If the previous operator was granted an exemption under § 9.72, you must provide to the Superintendent:

(1) Documentation demonstrating that you hold the right to operate within an NPS unit; and

- (2) The names and addresses of:
  - (i) The operator;
  - (ii) The mineral owner;
  - (iii) Any agents, assignees, designees, lessees, or other representatives of the operator;
  - (iv) The operator's representative responsible for the overall management of the proposed operations;
  - (v) The operator's representative responsible for field supervision of the proposed operations; and
  - (vi) The operator's representative responsible for emergency response for the proposed operations.

### Well Plugging

#### § 9.170 When must I plug my well?

Except as provided in § 9.171, you must plug your well when any of the following occurs:

- (a) Your drilling operations have ended and you have taken no further action on your well within 60 days;
- (b) Your well, which has been completed for production operations, is continuously inactive for a period of 1 year; or
- (c) The period approved in your operations permit to maintain your well in shut-in status has expired.

#### § 9.171 Can I get an extension to the well plugging requirement?

(a) You may apply for either an operations permit or a modification to your approved operations permit to maintain your well in a shut-in status for up to 5 years. The application must include:

- (1) An explanation of why the well is shut-in or temporarily abandoned and your future plans for utilization;
- (2) A demonstration of the mechanical integrity of both surface and downhole equipment such that there is no migration of fluid from any formation in which it originally occurred or from the surface to the well; and
- (3) A description of the manner in which your well, equipment, and area of operations will be maintained.

(b) Based on the information provided under this section, the Regional Director may approve your application to maintain your well in shut-in status for a period up to 5 years.

You may apply for additional extensions by submitting a new application under paragraph (a) of this section.

### Prohibitions and Penalties

#### § 9.180 What acts are prohibited under this subpart?

The following are prohibited:

- (a) Operating in violation of terms or conditions of a temporary access permit,

or an approved operations permit, or any provision of this subpart;

(b) Damaging federally owned or administered lands, waters, or resources of an NPS unit as a result of failure to comply with the terms or conditions of a temporary access permit, an operations permit, or any provision of this subpart;

(c) Conducting operations without a temporary access permit or operations permit;

(d) Failure to comply with any suspension or revocation order issued under this subpart; and

(e) Failure to comply with any applicable Federal, State, or local laws.

#### § 9.181 What enforcement actions can the NPS take?

If you engage in a prohibited act described in § 9.180:

(a) You may be subject to a fine or imprisonment, or both, in accordance with 36 CFR 1.3;

(b) The Superintendent may suspend your operations; or

(c) The Regional Director may revoke your approved temporary access permit or operations permit.

#### § 9.182 How do violations affect my ability to obtain a permit?

Until you comply with this subpart or the terms and conditions of an existing temporary access permit or operations permit, we will not consider any new requests for access to conduct operations within any NPS units.

### Reconsideration and Appeals

#### § 9.190 Can I, as operator, request reconsideration of NPS decisions?

Yes. If you disagree with a decision of the Regional Director under this subpart, you may file with the Regional Director a written statement describing the alleged factual or legal errors in the original decision and requesting that the Regional Director reconsider the decision. You must file your request for reconsideration within 60 calendar days after your receipt of the Regional Director's decision. The NPS will dismiss as untimely any request for reconsideration received more than 60 days after your receipt of the original decision.

#### § 9.191 How does the NPS process my request for reconsideration?

The Regional Director will review his or her original decision and, within 90 days after receipt of your appeal, provide you with a written statement reversing, affirming, or modifying that decision, unless the Regional Director notifies you that he or she needs additional time to review the original

decision. When issued, that written statement constitutes the Regional Director's final decision on the matter.

**§ 9.192 Can I appeal the Regional Director's decision?**

(a) If the Regional Director affirms or modifies his or her original decision after you file a request for reconsideration, you may then file an appeal with the NPS Director within 60 calendar days after your receipt of the Regional Director's decision under § 9.191.

(b) Your appeal must include a statement of exceptions specifying your specific disagreements with the Regional Director's final decision. If you do not file your statement of exceptions within 60 calendar days, your appeal will be dismissed, and the Regional Director's decision will constitute the NPS's final decision on the matter.

(c) If you timely file your statement of exceptions, the Regional Director will forward his or her decision and the record for the appeal to the NPS Director. The record will consist of NPS's official files on the proposed permit application, as well as any documents submitted by the parties upon which the Regional Director based his or her decision. The Regional Director will maintain that record under separate cover and will certify that he or she based the decision on that record. The Regional Director will make the record available to you at your request.

(d) If, upon review, the NPS Director considers the record inadequate, then the NPS Director may require additional appropriate documentation or information, or may remand the case to the Regional Director with appropriate instructions for further action.

(e) Within 45 calendar days from the date the NPS Director receives your statement of exceptions, the Director will make his or her decision in writing. If the Director requires more than 45 calendar days to reach his or her decision, then the Director will notify you and specify the reasons for the delay. The Director's written decision will include:

- (1) A statement of facts;
- (2) A statement of conclusions; and
- (3) An explanation of the reasons upon which he or she based his or her conclusions.

(f) No NPS decision under these regulations that is subject to appeal to the Regional Director or the Director shall be considered final agency action subject to judicial review under 5 U.S.C. 704 until the Director has rendered his or her decision on the matter. The decision of the NPS Director will constitute NPS's final agency action,

and no further appeal will lie in the Department from that decision.

**§ 9.193 Will filing a request for reconsideration or appeal stop the NPS from taking action under this subpart?**

(a) Except as provided for in paragraph (b) of this section, during the reconsideration and appeal processes, the decision at issue will be stayed (suspended). The decision will not become effective until the appeals process is completed.

(b) If NPS suspends your operation due to an emergency within your area of operation that poses an immediate threat of injury to federally owned or controlled lands or waters, you have a right to request reconsideration and appeal the decision under §§ 9.190 through 9.194, but the suspension will not be stayed until the threat is corrected.

**§ 9.194 What if the original decision was made by the Superintendent?**

Where the Superintendent has the authority to make the original decision, requests for reconsideration and appeals may be filed in the manner provided by the preceding sections, except that:

(a) The request for reconsideration will be filed with and decided by the Superintendent;

(b) The appeal will be filed with and decided by the Regional Director; and

(c) The Regional Director's decision will constitute the final agency action on the matter.

**Public Participation**

**§ 9.200 How can the public participate in the approval process?**

(a) Interested parties may view the publicly available documents at the Superintendent's office during normal business hours or by other means prescribed by the Superintendent. The availability for public inspection of information about the nature, location, character, or ownership of park resources will conform to all applicable law and implementing regulations, standards, and guidelines.

(b) The Superintendent will make available for public inspection any documents that an operator submits to the NPS under this subpart except those that you have identified as proprietary or confidential.

(c) For the information required in § 9.122 of this subpart, the operator and the owner of the information will be deemed to have waived any right to protect from public disclosure information submitted through FracFocus or another NPS-designated database. For information required under § 9.122 of this subpart that the

owner of the information claims to be exempt from public disclosure and is withheld from the NPS, a corporate officer, managing partner, or sole proprietor of the operator must sign and the operator must submit to the authorized officer an affidavit that:

(1) Identifies the owner of the withheld information and provides the name, address and contact information for a corporate officer, managing partner, or sole proprietor of the owner of the information;

(2) Identifies the Federal statute or regulation that would prohibit the NPS from publicly disclosing the information if it were in the NPS's possession;

(3) Affirms that the operator has been provided the withheld information from the owner of the information and is maintaining records of the withheld information, or that the operator has access and will maintain access to the withheld information held by the owner of the information;

(4) Affirms that the information is not publicly available;

(5) Affirms that the information is not required to be publicly disclosed under any applicable local, State, tribal, or Federal law;

(6) Affirms that the owner of the information is in actual competition and identifies competitors or others that could use the withheld information to cause the owner of the information substantial competitive harm;

(7) Affirms that the release of the information would likely cause substantial competitive harm to the owner of the information and provides the factual basis for that affirmation; and

(8) Affirms that the information is not readily apparent through reverse engineering with publicly available information.

(d) If the operator relies upon information from third parties, such as the owner of the withheld information, to make the affirmations in paragraphs (c)(6) through (8) of this section, the operator must provide a written affidavit from the third party that sets forth the relied-upon information.

(e) The NPS may require any operator to submit to the NPS any withheld information, and any information relevant to a claim that withheld information is exempt from public disclosure.

(f) If the NPS determines that the information submitted under paragraph (e) of this section is not exempt from disclosure, the NPS will make the information available to the public after providing the operator and owner of the information with no fewer than 10 business days' notice of the NPS's determination.

(g) The operator must maintain records of the withheld information until the later of the NPS's release of the operator's financial assurance, or 6 years after completion of hydraulic fracturing operations on Indian lands, or 7 years after completion of hydraulic fracturing operations on Federal lands. Any subsequent operator will be responsible for maintaining access to records required by this paragraph during its operation of the well. The operator will be deemed to be maintaining the records if it can promptly provide the complete and accurate information to NPS, even if the information is in the custody of its owner.

(h) If any of the chemical identity information required in § 9.122 of this subpart is withheld, the operator must provide the generic chemical name in the submission required by § 9.122 of this subpart. The generic chemical name must be only as nonspecific as is necessary to protect the confidential chemical identity, and should be the same as or no less descriptive than the generic chemical name provided to the Environmental Protection Agency.

#### Information Collection

##### § 9.210 Has the Office of Management and Budget approved the information collection requirements?

(a) The Office of Management and Budget (OMB) has reviewed and

approved the information collection requirements in 36 CFR part 9, subpart B, and assigned OMB Control Number 1024-XXXX. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number. We use the information collected to:

- (1) Evaluate proposed operations;
- (2) Ensure that all necessary mitigation measures are employed to protect park resources and values; and
- (3) Ensure compliance with all applicable laws and regulations.

(b) You may submit comments on any aspect of the information collection requirements to the Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Drive, Room 2C114, Mail Stop 242, Reston, VA 20192.

#### Subpart D—[Redesignated as Subpart C]

- 4. Redesignate subpart D as subpart C.

#### Subpart C—[Amended]

- 5. The authority citation for newly redesignated subpart C is revised to read as follows:

**Authority:** 16 U.S.C. 410hh; 16 U.S.C. 3101, *et seq.*; 16 U.S.C. 347; 16 U.S.C. 410bb; 16 U.S.C. 1131 *et seq.*; 54 U.S.C. 320301; 54 U.S.C. 100101, *et seq.*

- 6. In newly redesignated subpart C, redesignate §§ 9.80 through 9.89 as §§ 9.300 through 9.309.

- 7. In newly redesignated § 9.302, in paragraph (b)(2), remove the reference § 9.86 and add in its place the reference § 9.306.

- 8. In newly redesignated § 9.304, in paragraph (a), remove the reference § 9.84(b) and add in its place the reference § 9.304(b) and remove the reference § 9.83(b) and add in its place the reference § 9.303(b).

- 9. In newly redesignated § 9.306, in paragraph (a), remove the reference § 9.84 and add in its place the reference § 9.304.

- 10. In newly redesignated § 9.308, in paragraph (a), remove the reference § 9.86 and add in its place the reference § 9.306.

Dated: October 16, 2015.

**Karen Hyun,**

*Acting Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 2015-26812 Filed 10-23-15; 8:45 am]

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